Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1994

DOW CORNING CORPORATION,

Petitioner,

v.

MARIANN HOPKINS,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR A WRIT OF CERTIORARI

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78

QUESTIONS PRESENTED

1. May a federal appellate court after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ___, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993) uphold admission of expert scientific testimony when the district court refused to make any preliminary assessment of its scientific reliability and the proffered testimony met none of *Daubert's* reliability criteria?

2. In a diversity case, may a federal appellate court sustain a jury's punitive damage award, attacked on due process grounds, by adding standards to constrain discretion of California factfinders and of the district court that exist neither in California law nor federal law without violating the rules of *Erie R.R. Co. v. Tompkins* and *Browning-Ferris Indus. of Vermont v. Kelco Disposal, Inc.*, and impairing procedural due process guaranteed by the Fifth Amendment?

PARTIES

The parties are Dow Corning Corporation[1] and Mariann Hopkins.

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[1] Pursuant to Rule 29.1, petitioner states that Dow Corning Corporation is wholly owned by The Dow Chemical Corporation and by Corning Incorporated. The Dow Chemical Corporation's non-wholly-owned subsidiaries whose stock is publicly traded are Destec Energy, Inc., and Marion Merrell Dow, Inc. Corning Incorporated's non-wholly-owned subsidiaries are Calp, Iwaki Glass, Unilab Corp., Owens Corning.

TABLE OF CONTENTS

Page

QUESTIONS PRESENTED i

PARTIES ii

OPINION 1

JURISDICTION 1

CONSTITUTIONAL AND STATUTORY PROVISIONS 1

STATEMENT OF THE CASE 2

REASONS FOR GRANTING THE WRIT 12

A. *The National Importance of the Admissibility of Proffered Expert Scientific Testimony* 12

B. *The National Importance of the Standards of Judicial Review of Punitive Damages in Diversity Cases* ... 16

C. *The Ninth Circuit's Interpretation of Daubert Conflicts with the Opinions of Other Circuits* 18

D. *The Ninth Circuit Violated Browning-Ferris and Impaired Petitioner's Procedural Due Process Rights by Adding Standards to Constrain Discretion in Awarding Punitive Damages that do not exist in California or Federal Law* 21

E. *The Circuits are in Conflict on the Application of Haslip to Punitive Damage Awards in Diversity Cases* 25

CONCLUSION 28

APPENDIX A – Opinion ..... App. 1

APPENDIX B – Order Denying New Trial ..... App. 32

APPENDIX C – Judgment ..... App. 40

APPENDIX D – Order Denying Rehearing ..... App. 42

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Allied Chemical Corp. v. Daiflon, Inc., 449 U.S. 33, 66 L. Ed. 2d 193, 101 S. Ct. 188 (1980) 23

Auster Oil & Gas, Inc. v. Stream, 835 F.2d 597 (5th Cir. 1988) 24

Bankers Life & Casualty Co. v. Crenshaw, 486 U.S. 71, 108 S. Ct. 1645, 100 L. Ed. 2d 62 (1988) 23

Bonn v. Puerto Rico Int'l Airlines, Inc., 518 F.2d 89 (1st Cir. 1975) 24

Bourjaily v. United States, 483 U.S. 171, 99 F.2d 144, 107 S. Ct. 2775 (1987) 11

Brock v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307 (5th Cir.), *modified*, 884 F.2d 1511 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046, 108 L. Ed. 2d 646 110 S. Ct. 1511 (1990) 21

Browning-Ferris Indus. v. Kelco Disposal, Inc., 492 U.S. 257, 106 L. Ed. 2d 219, 109 S. Ct. 2909 (1989) 17, 21, 23, 25, 26

Celotex Corp. v. Catrett, 477 U.S. 317, 91 L. Ed. 2d 265, 100 S. Ct. 2548 (1986) 20

Community Television Services, Inc. v. Dresser Industries, Inc., 435 F. Supp. 214 (D.S.D. 1977), *aff'd*, 586 F.2d 637 (8th Cir. 1978) 24

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. ___, 125 L. Ed. 2d 469, 113 S. Ct. 2786 (1993) ..... *passim*

Elkins v. Richardson-Merrell, Inc., 8 F.3d 1068 (6th Cir. 1993) 19

TABLE OF AUTHORITIES – Continued

Page

Erie R.R. Co. v. Tompkins, 304 U.S. 64, 58 S. Ct. 817, 82 L. Ed. 1188 (1938) 26

Fairmount Glass Works v. Cub Fork Coal Co., 287 U.S. 474, 77 L. Ed. 439, 53 S. Ct. 252 (1933) 23

Gertz v. Robert Welch, Inc., 418 U.S. 323, 41 L. Ed. 2d 789, 94 S. Ct. 2997 (1974) 22

Honda Motor Co., Ltd. v. Oberg, ___ U.S. ___, 129 L. Ed. 2d 336, 114 S. Ct. 2331 [62 U.S.L.W. 4627] (1994) 16, 18, 25

Hopkins v. Dow Corning Corp., 33 F.3d 1116 (1994) 1

In Re Joint E. & S. Dist. Asbestos Litig., 129 B.R. 710 (E & S D.N.Y. 1991), *vacated on other grounds*, 982 F.2d 721 (2d Cir. 1992) 16

Latham Seed Co. v. Nickerson American Plant Breeders, Inc., 978 F.2d 1493 (8th Cir. 1992) 27

Mattison v. Dallas Carrier Corp., 947 F.2d 95 (4th Cir. 1991) 25

Mekdeci v. Merrill National Lab., 711 F.2d 1510 (11th Cir. 1983) 14

Nairn v. National R.R. Passenger Corp., 837 F.2d 565 (2d Cir. 1988) 24

O'Conner v. Commonwealth Edison Co., 13 F.3d 1090 (7th Cir. 1994) 19

Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 113 L. Ed. 2d 1, 111 S. Ct. 1032 (1991) 9, 22, 24, 25, 27

Porter v. Whitehall Laboratories, Inc., 9 F.3d 607 (7th Cir. 1993) 20

TABLE OF AUTHORITIES – Continued

Page

Sorenson v. Shaklee Corp., 31 F.3d 638 (8th Cir. 1994) 20

Superbird Farms, Inc. v. Perdue Farms, Inc., 970 F.2d 238 (7th Cir. 1992) 24

Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. ___, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992) 21

United States v. Bonds, 12 F.3d 540 (6th Cir. 1993) 21

United States v. Martinez, 3 F.3d 1191 (8th Cir. 1993) 21

United States v. Rincon, 11 F.3d 922 (9th Cir. 1993) (second opinion after remand.) 14

United States v. Rincon, 984 F.2d 1003 (9th Cir.), *vacated and remanded for further consideration in the light of Daubert*, ___ U.S. ___, 126 L. Ed. 2d 12, 114 S. Ct. 41 (1993) 14

Wheat v. Pfizer, Inc., 31 F.3d 340 (5th Cir. 1994) 19

Whitely v. OKC Corp., 719 F.2d 1051 (10th Cir. 1983) 24

STATE CASES

Adams v. Murakami, 54 Cal.3d 105, 284 Cal.Rptr. 318 (1991) 22

Neal v. Farmers Ins. Exchange, 21 Cal.3d 910, 148 Cal.Rptr. 389 (1978) 23

FEDERAL STATUTES

28 U.S.C. § 1254(1) 1

28 U.S.C. § 1332 1

TABLE OF AUTHORITIES – Continued

Page

Federal Rules of Civil Procedure, Rule 50(b) 26

Federal Rules of Civil Procedure, Rule 59 ..... 1, 17, 23, 26, 27

Federal Rules of Evidence, Rule 104(a) 1, 10, 11, 18

TREATISES AND LAW REVIEW ARTICLES

California Approved Jury Instructions: Civil No. 14.72.2 (rev. ed. 1989) 8

GAO Briefing Report to the Chairman, Subcommittee on Commerce, Consumer Protection and Competitiveness, Committee on Energy and Commerce, House of Representatives: Products Liability Extent of "Litigation Explosion" in Federal Courts Questioned, 2-3, 20-28 (1988) 16

J.B. Weinstein, "Ethical Dilemmas in Mass Tort Litigation," 88 *Nw. U.L. Rev.* 469 (1994) 13

J. Sanders, "The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts," 43 *Hastings L.J.* 301 (1992) 13

L. Brickman, "On the Relevance of the Admissibility of Scientific Evidence: Tort System Outcomes are Principally determined by Lawyers' Rates of Return," 15 *Cardozo L. Rev.* 1755 (1994) 13

P. Huber, "Safety and the Second Best: The Hazards of Public Risk Management in the Courts," 85 *Colum. L. Rev.* 277 (1985) 13

S. Sugarman, "Doing Away with Tort Law," 73 *Calif. L. Rev.* 555 (1985) 13

OPINION

The opinion of the United States Court of Appeals for the Ninth Circuit is reported in 33 F.3d 1116 (1994). A copy of the slip opinion is annexed hereto as Appendix A ("App. 1").

JURISDICTION

The opinion of the court of appeals was filed on August 26, 1994. A timely petition for rehearing and suggestion for *en banc* consideration was denied on October 11, 1994. App. 42. (Appendix D). Jurisdiction of the district court was based on diversity of citizenship. 28 U.S.C. § 1332. Jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS

The Fifth Amendment to the United States Constitution provides, in pertinent part: "No person shall . . . be deprived of . . . property, without due process of law. . . . "

The applicable portions of Rule 104(a) of the Federal Rules of Evidence and Rule 59 of the Federal Rules of Civil Procedure are set forth in footnotes to the text hereof.

STATEMENT OF THE CASE

Pretrial. Respondent filed her personal injury action in the federal district court, invoking diversity jurisdiction, in December, 1988. She alleged that her rare autoimmune disease (mixed connective tissue disease "MCTD"), definitely diagnosed in 1979, was caused by prescription mammary prostheses manufactured by petitioner and first implanted in her by Dr. Karl Bollinger in 1976 to reconstruct her breasts after a bilateral mastectomy. ER 1.[2]

Petitioner moved for summary judgment on the grounds that the respondent's evidence of a causal connection between her prostheses and her disease was insufficient to create a triable issue of fact and that her personal injury claim was barred by the applicable California's one-year statute of limitations. The motion was denied. After extensive discovery, petitioner filed a motion *in limine* to exclude the testimony of respondent's three designated expert causation witnesses, Drs. Marc Lappé, Nir Kossovsky and Frank Vasey, because none of their opinions was scientifically reliable or based on a methodology or technique accepted by any relevant scientific community.

The evidence before the district court in ruling on the pre-trial motion revealed the following uncontroverted facts:

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[2] Throughout this Petition, the following abbreviations are used: "ER" (Excerpts of the Record filed with the Ninth Circuit); "RT" (Reporter's Transcripts), and "App." refers to the Appendix attached hereto.

In mid-1975, respondent had a number of symptoms that were consistent with early signs of MCTD. Dr. Pelfini, her internist, ordered a test for autoimmune disease that proved inconclusive. In October, 1976, Dr. Karl Bollinger performed a bilateral subcutaneous mastectomy on respondent and, as part of the same surgery, reconstructed her breasts by using two prescription gel-filled silicone mammary prostheses manufactured by petitioner. In 1977, Dr. Bollinger replaced those prostheses with a second set, also manufactured by petitioner, due to post-surgical complications unrelated to the prostheses. When in 1979 respondent continued to suffer from the symptoms that Dr. Pelfini recorded in 1975, he referred her to Dr. Gospe, a rheumatological specialist, who ordered another autoimmune disease test. That test was positive. Dr. Gospe's medical records state that respondent's MCTD had begun between 2½ to 3 years before he saw her. Dr. Gospe continued to treat her for her rheumatological disorder for the next 10 years.

In 1985, after petitioner had received some case reports hypothesizing immunological sensitivity to gel-filled prostheses, it rewrote its package inserts accompanying the prostheses shipped to prescribing physicians. To earlier described possible adverse effects, the new insert added: "There have been reports of suspected immunological sensitization or hyperimmune response to silicone mammary implants. . . . [C]laims from clinical use of silicone prostheses in humans suggests that immunological responses or sensitization in mammary prosthesis can occur. . . . " ER CC. Physicians were warned to remove the prostheses if sensitization was suspected. *Ibid.*

Because her prostheses were sagging, respondent consulted Dr. Bollinger in January, 1986, and she thereupon decided to have her second set of implants replaced. Although Dr. Bollinger had read petitioner's package inserts and he knew that she was suffering from MCTD, he told petitioner nothing about petitioner's warning of possible immunological sensitivity to gel-filled prostheses. When Dr. Bollinger undertook replacement surgery on February 20, 1986, he discovered that her second set of implants had ruptured. Until then, he and the respondent had assumed that the replacement would be a simple procedure under local anesthetic. He immediately told respondent what he had discovered and explained to her that removal of the damaged prostheses would require lengthy surgery under general anesthetic. After she was generally anesthetized, he removed the prostheses and replaced them with her third set of prostheses manufactured by petitioner.

Shortly after that surgery, Dr. Bollinger told respondent that the prostheses had been returned to petitioner for analysis by its laboratory and that he would thereafter receive a laboratory report. Respondent asked to read the report when he received it. She thereafter read the report which described the methodology of the analysis and concluded with the opinion that the analysis revealed "no evidence to indicate that any damage was manufacture [sic] related." ER DD.

Although her third set of implants had not failed, she was dissatisfied with her appearance and transferred her care from Dr. Bollinger to Dr. Tavis. Dr. Tavis explanted her third set and implanted her fourth set of petitioner's prostheses in late 1986. In 1991, she had her fourth set

removed by Dr. Shaw, who performed a bilateral reconstruction from her own tissue. ER B.

None of her medical records stated any cause of her MCTD or hypothesize any connection between her disease and her prostheses.

Dr. Lappé has a Ph.D degree in experimental pathology. He is not a chemist, an immunologist, an epidemiologist, or a toxicologist, and he is not qualified to diagnose or treat human beings. His experimental pathology research involved animal studies, none of which was recent, and his own research had not included an investigation of silicone products. His opinion was based on his examining 226 laboratory studies out of 869 laboratory studies produced by petitioner during discovery. These were tests of the safety of silicone and silicone products used in manufacturing mammary prostheses; they were performed by petitioner's laboratory and outside laboratories. Although none of the researchers who performed those studies found relevant adverse effects on immune systems, Dr. Lappé disagreed. He testified that respondent's 1976 and 1977 prostheses "could have contributed to the reaction but was not a primary cause of this reaction"; he said that a causal link between the two is "an open question in the strict scientific sense of establishing causality."

Dr. Kossovsky's deposition revealed that he is an experimental pathologist, not an immunological pathologist, rheumatologist, a chemist, or an epidemiologist. His opinion was based on one study that he had conducted in which he had injected guinea pigs with a combination of silicone and animal protein in which he observed an

immunological reaction in the animals, and his review of some slides of respondent's tissue in which he believed he saw evidence of bioreactivity. He conceded that the results of animal studies cannot be readily extrapolated to human beings. Dr. Kossovsky testified that there is "no direct evidence of a causal connection between the two [autoimmune disease and breast prostheses], but that is one of the chronic problems in making a medical diagnosis."

Dr. Vasey's deposition revealed that he is an academic rheumatologist and that he is not qualified in any other relevant scientific field. His opinion was based on his own clinical observations of some of his patients. He said that the risk of some connection between silicone and MCTD was not quantifiable.

In denying petitioner's motions for summary judgment and to exclude the testimony of respondent's causation experts, the district court declined to make any Rule 104(a) preliminary assessment of the scientific reliability of the proffered testimony. The court expressed the view that the question of scientific reliability of the expert witnesses' testimony would be left to the jury.

Trial. After overruling petitioner's repeated objections to the testimony of respondent's expert causation witnesses based on the lack of any scientific foundation for their testimony, Drs. Lappé, Kossovsky and Vasey testified extensively at trial. Although their confidence in their opinions had increased since their depositions were taken, the foundation for their testimony was unchanged.

During the trial, the testimony of Drs. Kossovsky and Vasey and the testimony of petitioner's highly qualified

expert scientific witnesses agreed on one point: The cause of MCTD is not known. All that is scientifically known is that MCTD is a rare autoimmune disease that presents itself in men and women in their thirties and forties, that women are more susceptible to the disease than men, and that there is a genetic component.

Respondent produced no epidemiological evidence. Petitioner produced epidemiological studies and the testimony of Dr. Lamm, a well-qualified epidemiologist, who testified that none of the epidemiology studies to date had revealed any causal relationship between women who had breast prostheses (of all kinds by all manufacturers) and MCTD.[3]

At the conclusion of the liability phase of the case, petitioner moved for a directed verdict, which was denied. The jury returned its special and general verdicts finding petitioner liable for respondent's personal injuries. ER 283. Thereafter, the jury returned special verdicts awarding respondent total compensatory damages of $840,000. ER 299. The court then gave the jury instructions on punitive damages set forth in full in the margin.[4]

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[3] Dr. Lamm testified that, based on the number of women in the country who had such prostheses, epidemiologists would have expected at least 100 cases of MCTD to be reported in implant recipients if a causal connection existed, but, as of 1991, there was not even one such case reported in the United States.

[4] "You must now determine whether you should award punitive damages against defendant Dow Corning Corporation, for the sake of example and by way of punishment. Whether punitive damages should be imposed, and if so, the amount thereof, is left to your sound discretion, exercised without passion or prejudice.

The jury returned its verdict awarding $6,500,000 in punitive damages. ER 299. Judgment was entered in accordance with the verdicts on January 9, 1992. ER 309, App. 40. (Appendix C).

Petitioner moved for judgment notwithstanding the verdicts and, alternatively, for a new trial, on grounds that included the following: (1) The testimony of respondent's expert causation witnesses was insufficient to support the verdicts because none of their opinions was based on scientifically acceptable methodology, none of their methods was accepted by a relevant scientific community, and none was scientifically reliable. (2) The jury's awards of compensatory damages for medical expenses, loss of income, and pain and suffering were not sustained by the evidence because those awards included compensation for injuries and losses that were not causally related to her MCTD, the basis of her personal injury claim, and, in any event, were foreclosed by limitations. (3) The punitive damage award was excessive and bore no reasonable relationship to compensable damages. The

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"If you determine that punitive damages should be assessed against the defendant, in arriving at the amount of such an award, you must consider: (1) The reprehensibility of the conduct of the defendant. (2) The amount of punitive damages which will have a deterrent effect on the defendant in the light of defendant's financial condition. (3) That the punitive damages must bear a reasonable relation to the injury, harm, or damage actually suffered by the plaintiff." ER 302. The instruction was taken verbatim from the *California Approved Jury Instructions*: Civil No. 14.72.2 (rev. ed. 1989).

Immediately after giving that instruction, the district court told the jury: "The parties have stipulated that the net worth of defendant Dow Corning Corporation is $948,500,000." ER 302.

district court denied the motions on May 8, 1992. App. 32. (Appendix B).

Appeal. The case was briefed and argued after this Court had granted *certiorari* in *Daubert*, but before that opinion had come down. Petitioner argued, *inter alia*, that the district court prejudicially erred dènying summary judgment and in admitting over objection the testimony of respondent's expert causation witnesses because their testimony did not meet the criteria for admissibility under the *Frye* test, which was then the law of the Ninth Circuit, or the scientific reliability standards that had been accepted in the Second and Third Circuits.[5]

Petitioner attacked the jury's award of compensatory damages because the amounts vastly exceeded any damage that she could have suffered from such claims, if any, that were not barred by California limitation's law and because those damages were not proved to be causally related to her MCTD. It challenged the punitive damage award because it was grossly excessive, bore no understandable relationship to compensatory damages that could have been properly awarded, and the standards and procedure used to guide the jury's discretion in awarding punitive damages did not meet the constitutional minima required by *Pacific Mut. Life Ins. Co. v.*

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[5] After citing the relevant authorities from the Ninth and other circuits, petitioner urged reversal because respondent's testimony on the issue of causation "was not based on accepted scientific standards and was not reliable and because [respondent] could not meet her burden of proving that the prostheses caused the diseases and disorders of which she complained." Appellant's Opening Brief at 49.

Haslip, 499 U.S. 1, 113 L. Ed. 2d 1, 22, 111 S. Ct. 1032 (1991).[6] Appellant's Opening Brief at 57.

The case was orally argued on June 18, 1993. After the case was submitted, this Court decided *Daubert*, and the parties filed supplemental briefs discussing the impact of *Daubert* on the pending appeal. Petitioner's supplemental brief pointed out that the district court had declined to conduct the preliminary assessment of scientific reliability required by *Daubert*, and the testimony of respondent's expert witnesses did not meet the reliability criteria therein described. The panel issued its opinion on August 26, 1994.

Petitioner timely filed its petition for rehearing and suggestion for *en banc* consideration. The petition called the court's attention to the irreconcilability of the panel's holding and quoted *Daubert's* requirement that a Rule 104(a) preliminary assessment of scientific reliability was required:

> Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the

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[6] Petitioner also brought to the court's attention the pendency of two cases in which hearings had been granted by the California Supreme Court challenging, on due process grounds, California's procedures and standards for awarding punitive damages by juries. The petitions were later dismissed without explanation.

> reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue. 509 U.S. at ___, 125 L. Ed. 2d at 482, 113 S. Ct. at ___.[7]

Petitioner also quoted from the panel's opinion:

> "[Petitioner] asserts that the district court erred in not holding a formal hearing. We disagree. The district court is not required to hold a Rule 104(a) hearing, but rather must merely make a determination as to the proposed expert's qualifications." 33 F.3d at 1124.

The petition also pointed out that the opinion relied on procedures and on factual assumptions that were

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[7] Footnote 11 omitted. Footnote 10 to the quoted passage states, in pertinent part:

> Rule 104(a) provides:
>
> "Preliminary questions concerning the qualification of a person to be a witness . . . or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b) [pertaining to conditional admissions]. . . . " See *Bourjaily v. United States*, 483 U.S. 171, 175-76, 99 F.2d 144, 107 S. Ct. 2775 (1987). These matters should be established by a preponderance of proof.

Bourjaily concerned the admissibility of hearsay statements by an alleged co-conspirator implicating the defendant in a drug sale. The court explained that before the evidence could be admitted over objection, the court must previously "have found it more likely than not that the technical issues and policy concerns addressed by the Federal Rules of Evidence have been afforded due consideration." 483 U.S. at 175, 97 L. Ed. 2d at 152, 107 S. Ct. at 2778.

unsupported by the record in affirming the punitive damage award.[8]

The petition for rehearing was denied on October 11, 1994. App. 42. (Appendix D).

REASONS FOR GRANTING THE WRIT

A. The National Importance of the Admissibility of Proffered Expert Scientific Testimony

Hundreds of products liability cases are currently pending in federal courts in which the key liability issue is whether a prescription medical device or drug is causally related to plaintiff's diseases or illnesses, and, in each of them, the crucial liability question is the admissibility of expert scientific testimony on causation. The judgment in the district court in this case triggered the explosion of breast implant litigation. Before then, only a handful of

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[8] In affirming punitive damages, the petition explained that the opinion stated a number of assumed facts that were supported only by the arguments of respondent's counsel. After stating that petitioner's prostheses had been implanted in thousands of women, the opinion states: "Each of these women was at risk of encountering the same fate from which Hopkins suffered"; and "the evidence that [petitioner] gained financially from its conduct, may properly be considered in imposing an award of punitive damages." 33 F.3d at 1127. There was no evidence that any women, let alone thousands, were at risk of MCTD who had been implanted with petitioner's prostheses. The record contradicts the statement that petitioner gained financially; the evidence was that petitioner lost money on its sales of mammary prostheses.

breast implant cases had been filed against any manufacturer of such products anywhere in the country. Thereafter, state and federal courts have been inundated with cases, including class actions, against all manufacturers of mammary prostheses in which plaintiffs claim that whatever injury, disease or illness from which they suffer is causally related to their implants.

Mass product liability litigation, whether involving prescription drugs and medical devices or non-prescription products, share common characteristics and follow a well-documented pattern.[9] The genesis of such litigation

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[9] Numerous scholarly articles have discussed the features of the mass tort litigation phenomenon. Well-known examples of the products involved in the phenomenon include Bendectin, the Dalkon Shield, DES, swine flu vaccine, Agent Orange, and asbestos. The forces that have converged to create the situation include the intensity of media coverage, the strong organization of the plaintiffs' product litigation bar, the legalization of lawyers soliciting clients in such cases through media advertising, and the lure of potential multimillion dollar punitive damage verdicts against target defendants who have or are believed to have deep pockets. A few examples of the relevant literature are: L. Brickman, "On the Relevance of the Admissibility of Scientific Evidence: Tort System Outcomes are Principally Determined by Lawyers' Rates of Return," 15 *Cardozo L. Rev.* 1755 (1994); J.B. Weinstein, "Ethical Dilemmas in Mass Tort Litigation," 88 *Nw. U.L. Rev.* 469, 480 (1994) ("[t]he speed with which the number of breast implant cases exploded on the scene is attributable in part to a well-organized plaintiffs' bar, which now has the capital, organizational skills, and advertising techniques to seek clientele"); P. Huber, "Safety and the Second Best: The Hazards of Public Risk Management in the Courts," 85 *Colum. L. Rev.* 277 (1985); S. Sugarman, "Doing Away with Tort Law," 73 *Calif. L. Rev.* 555 (1985); J. Sanders, "The Bendectin Litigation: A Case Study in the Life Cycle of Mass Torts," 43 *Hastings L.J.* 301 (1992).

is usually one case in which a plaintiff has won a jury verdict that included large punitive damages against the manufacturer of a product and in which the case has received extensive media coverage. Breast implant litigation has followed the same pattern; it strikingly resembles the history of the bendectin litigation, the prescription product involved in *Daubert*.[10]

In all of these cases there is always a temporal connection between the claimed injury, disease or illness and the use of or exposure to the product. The key liability question is whether the product caused the plaintiff's condition, proof of which requires expert scientific testimony on that ultimate fact. The admissibility of proffered expert testimony is thus crucial to the outcome of the case.[11]

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[10] The Bendectin litigation began with a 1977 Florida lawsuit in which a mother claimed that her taking prescribed Bendectin during her pregnancy caused birth defects in her infant. *Mekdeci v. Merrill National Lab.*, 711 F.2d 1510 (11th Cir. 1983). *Mekdeci* received substantial media attention, and shortly thereafter, hundreds of lawsuits were filed in state and federal courts by women whose infants had birth defects. The same phenomenon occurred in breast implant litigation, except that media attention has been far more extensive and prolonged.

[11] The importance of the proper interpretation and application of *Daubert*, of course, is not limited to product liability litigation. The same issue arises in every case, civil or criminal, in which expert scientific or quasi-scientific testimony will be relied upon to prove an essential fact. *See, e.g. United States v. Rincon*, 984 F.2d 1003 (9th Cir.), *vacated and remanded for further consideration in the light of Daubert*, ___ U.S. ___, 126 L. Ed. 2d 12, 114 S. Ct. 41 (1993); *United States v. Rincon*, 11 F.3d 922 (9th Cir. 1993) (second opinion after remand.)

Even before *Daubert*, it should have been clear that trial judges have the duty to make a preliminary assessment of the admissibility of proffered expert testimony. Some trial judges, uncomfortable in the realm of scientific technique and methodology, have failed to perform that duty even though the same judges routinely perform their gatekeeping duty in deciding admissibility questions that are as hard.[12] The *Daubert* Court recognized that reality in observing: "We are confident that federal judges possess the capacity to undertake this review." 509 U.S. at ___, 125 L. Ed. at 482, 113 S. Ct. at ___. Whatever doubts individual judges may from time-to-time have entertained about their capacity to undertake a preliminary assessment of the scientific reliability of expert testimony, they are better situated to make that determination than jurors because jurors, unlike federal judges, are not empowered to appoint their own experts.

The briefs of the parties and the cascade of *amicus curiae* briefs filed in *Daubert* leave no doubt about the depths of concern expressed by litigants, scientists, and interested members of the general public that district judges must meticulously perform their gatekeeping role to prevent "junk science" from being introduced into evidence.

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[12] For example, trial judges regularly rule on the admissibility of hearsay even though the application of the hearsay rule and its exceptions is often difficult. The concerns about the admissibility of hearsay testimony are similar to the concerns expressed in *Daubert* about the admissibility of proffered scientific expert testimony: Is the testimony reliable? Does its probative value outweigh its prejudicial effect?

Strong considerations of public policy dictate that the preliminary assessment be made before trial, especially in cases, like this one, that have the potential for generating mass product liability litigation, the costs of which are astronomical.[13] If a plaintiff is not able to carry her burden of proof on the causation issue before trial, the action should end in the district court, thereby permitting the admissibility question to be reviewed on appeal by the fastest available means at the least cost to the litigants and to the judiciary.

B. The National Importance of the Standards of Judicial Review of Punitive Damages in Diversity Cases

This Court has repeatedly recognized the constitutional dimensions of the raging debates over unconstrained jury discretion in awarding punitive damages. The problem was succinctly posed in *Honda Motor Co.,*

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[13] The overburden on judicial systems from mass product liability actions can scarcely be overestimated. The General Accounting Office published a study for the decade 1976-1986 that toxic litigation (Bendectin, Dalkon Shield, and asbestos) accounted for over 60 percent of the total growth in filings during that decade, and those estimates did not include the broader range of products with the same characteristics. *GAO Briefing Report to the Chairman, Subcommittee on Commerce, Consumer Protection and Competitiveness, Committee on Energy and Commerce, House of Representatives: Products Liability Extent of "Litigation Explosion" in Federal Courts Questioned,* 2-3, 20-28 (1988). *See, e.g., In Re Joint E.&S. Dist. Asbestos Litig.,* 129 B.R. 710, 953 (E&S. D.N.Y. 1991), *vacated on other grounds,* 982 F.2d 721 (2d Cir. 1992) (excluding legal fees, asbestos litigation cost between 13 and 16 billion dollars).

Ltd. v. Oberg, ___ U.S. ___, 129 L. Ed. 2d 336, 114 S. Ct. 2331 [62 U.S.L.W. 4627] (1994):

> Punitive damages pose an acute danger of arbitrary deprivation of property. Jury instructions typically leave the jury with wide discretion in choosing amounts, and the presentation of evidence of a defendant's net worth creates the potential that juries will use their verdicts to express biases against big businesses, particularly those without strong local presences. ___ U.S. at ___, 129 L. Ed. 2d at 349, 114 S. Ct. ___, 62 U.S.L.W. at 4631.

This case exactly fits that description. Petitioner is a big corporation with no significant presence in California. Juries in California are given great discretion in imposing punitive damages. Unlike Alabama and Oregon, California law provides no post-trial constraints on such awards. Because this is a diversity case, judicial review of a punitive damage award is controlled by federal, not state law. Under *Browning-Ferris Indus. v. Kelco Disposal, Inc.*, 492 U.S. 257, 106 L. Ed. 2d 219, 109 S. Ct. 2909 (1989), a federal court reviewing a punitive damage award in a diversity case must follow Rule 59 of the Federal Rules of Civil Procedure.[14] The Ninth Circuit applied neither the law of California nor Rule 59. Instead, it applied the post-trial constraints adopted by the State of Alabama that do not exist either in California law or federal procedural

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[14] Rule 59 provides, in pertinent part: "(a) A new trial may be granted to all or any of the parties and on all or part of the issues (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States. . . . "

rules. The court could not avoid the due process issue by amending California law and federal procedure rules.

Thus, this case presents the question: What standards of review are required to satisfy procedural due process when a jury award of punitive damages in a diversity case is attacked on due process grounds?[15]

C. The Ninth Circuit's Interpretation of *Daubert* Conflicts with the Opinions of Other Circuits

The Ninth Circuit specifically held that the only assessment that the district court was required to make before admitting the testimony of respondent's expert witnesses was the witnesses' qualification to testify and that no Rule 104(a) hearing is required. The panel undertook no review of the evidence presented by respondent to controvert petitioner's summary judgment motion challenging the sufficiency of her causation evidence to raise a triable issue of fact. If it had compared respondent's deposition testimony on causation with the requirements of *Daubert*, it should have been evident that her causation evidence was insufficient to permit her to go to trial. Without any comparison of the testimony that respondent's experts actually gave at pretrial and trial, the court summarily held that the respondent's witnesses

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[15] The Court noted the importance of that question in the context of its own review of state court judgments in *Honda Motor Co.*: "This case does not pose the more difficult question of what standard of review is constitutionally required." ___ U.S. at ___ n.10, 129 L. Ed. 2d at 350 n.10, 114 S. Ct. at ___, 62 U.S.L.W. at 4631.

were qualified and that their testimony was based on scientifically valid methodology. 33 F.3d at 1125.[16]

The Fifth, Sixth, Seventh and Eighth Circuits have all upheld summary judgments when the plaintiff's expert scientific witnesses did not meet *Daubert's* criteria for admissibility. *E.g., Wheat v. Pfizer, Inc.*, 31 F.3d 340 (5th Cir. 1994) (manufacturers of two prescription drugs prevailed on summary judgment in a wrongful death diversity case in which plaintiff claimed that the decedent's hepatitis was caused by the drugs because the proffered testimony of plaintiff's expert witness was based only on the witness' hypothesis that had not been subjected to peer review or publication and was unsupported by accepted methodology); *Elkins v. Richardson-Merrell, Inc.*, 8 F.3d 1068, 1070-71 (6th Cir. 1993) (summary judgment for defendant affirmed in a Bendectin case because plaintiff's affidavit in opposition to summary judgment failed to show that the expert causation testimony was sufficiently reliable to raise a triable issue of fact); *O'Conner v. Commonwealth Edison Co.*, 13 F.3d 1090 (7th Cir. 1994) (testimony of plaintiff's expert witness that his cataracts

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[16] The opinion relied on the arguments of counsel, not on the testimony in the record. It recites the supposed expertise of Dr. Lappé and states that Dr. Kossovsky testified that "[t]he methodology used by Hopkins' experts in reaching their conclusions dated back to 1976"; and it also said that Dr. Kossovsky's opinion was based on "his participation in the preliminary epidemiological study involving over 200 women, and that Dr. Vasey based his opinion on "preliminary results of an epidemiological study and medical literature." 33 F.3d at 9787. The record supports none of those statements, as petitioner pointed out in its petition for rehearing.

were caused by overexposure to radiation from defendant's nuclear power plant resting only on the expert's observation and opinion, but otherwise unsupported by any scientific methodology was inadmissible); *Sorensen v. Shaklee Corp.*, 31 F.3d 638 (8th Cir. 1944) (summary judgment for defendant affirmed in an action claiming that the mental retardation of infants was caused by parents' ingestion of a product containing a chemical residue that was teratogenic or mutagenic; although qualifications of plaintiffs' expert witnesses to testify were unchallenged, their testimony was not based on a tested methodology and did not meet *Daubert's* reliability criteria).[17] *Porter v. Whitehall Laboratories, Inc.*, 9 F.3d 607 (7th Cir. 1993) (plaintiff claimed that his kidney failure was caused by defendant's prescribed drug; summary judgment for the pharmaceutical company was affirmed because the proposed expert testimony was not properly grounded on the scientific method).

The method that respondent's expert witnesses used in reaching their conclusions had never been tested by anyone or peer reviewed. The risks of error in their methodology were neither quantified nor quantifiable, and none had been accepted by any scientific community. Accordingly, petitioner's summary judgment motion should have been granted. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 91 L. Ed. 2d 265, ___, 100 S. Ct. 2548, 2553

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[17] The *Sorensen* court explained that the plaintiff's expert witnesses had turned scientific analysis on its head: "Instead of reasoning from known facts to reach a conclusion, the experts here reason from an end result in order to hypothesize what needed to be known but was not." 31 F.3d at 649.

(1986). Petitioner's trial objections to the admission of respondents' expert witnesses should have been sustained.

When expert scientific testimony has been admitted, over objection, at trial, other circuits have meticulously compared the testimony actually given with the reliability criteria of *Daubert* to determine whether the evidence was sufficiently reliable to go to the jury. The Ninth Circuit did not do so. *Contrast United States v. Bonds*, 12 F.3d 540 (6th Cir. 1993); *United States v. Martinez*, 3 F.3d 1191 (8th Cir. 1993).[18]

D. The Ninth Circuit Violated *Browning-Ferris* and Impaired Petitioner's Procedural Due Process Rights by Adding Standards to Constrain Discretion in Awarding Punitive Damages that do not Exist in California or Federal Law

Although the opinion stated the requirements of *Browning-Ferris* (the district court had to decide whether the jury's punitive damage verdict was within the confines set by California law, and judicial review of the award is controlled by Federal Rule of Civil Procedure 59), it thereafter violated the very principles recited. It

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[18] Even before *Daubert*, other courts examined expert scientific testimony in detail to decide whether it was sufficient to go to the jury. *E.g.*, *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. ___, 121 L. Ed. 2d 47, 113 S. Ct. 84 (1992); *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 315 (5th Cir.), *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046, 108 L. Ed. 2d 646, 110 S. Ct. 1511 (1990). *Turpin* and *Brock* were cited with approval in *Daubert*, 509 U.S. at ___, 125 L. Ed. 2d at 484-85.

did not examine either California law or federal law. Instead, it applied the post-trial judicial standards of review adopted by Alabama set forth in *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22, 113 L. Ed. 2d 1, 22, 111 S. Ct. 1032, 1054 (1991).

A California jury receives little more instruction than that described in *Gertz v. Robert Welch, Inc.*, 418 U.S. 323, 350, 41 L. Ed. 2d 789, 94 S. Ct. 2997 (1974):

> In most jurisdictions jury discretion over the amounts awarded is limited only by the general rule that they not be excessive. Consequently, juries assess punitive damages in wholly unpredictable amounts bearing no necessary relation to the actual harm caused.

The sole guidance given a California jury invited to award punitive damages is contained in the jury instruction given in this case.[19] California has not adopted any of Alabama's post-trial standards of judicial review.[20]

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[19] The entire text of the instruction is quoted in n.4 at pp. 4-5, *supra*. In *Adams v. Murakami*, 54 Cal.3d 105, 112, 284 Cal.Rptr. 318 (1991), the court candidly described the breadth of the jury's discretion in determining the amount of punitive damages to award:

> The determination of whether an award is excessive is admittedly more art than science. "The channeling of just the correct quantum of bile to reach the correct level of punitive damages is, to put it mildly, an unscientific process complicated by personality differences." [Citation omitted.]

[20] The *Adams* court recognized that California's post-trial review may not meet *Haslip*'s constitutional minima, but it postponed that decision because it had reversed on other grounds. 54 Cal.3d at 118-19 n.9.

Post-trial scrutiny is limited to examining the amount of the award to ascertain whether it appears to be excessive as a matter of law or whether it is so grossly disproportionate to compensatory damages and to the particular conduct charged as to raise a presumption that it is the result of passion or prejudice. *Neal v. Farmers Ins. Exchange*, 21 Cal.3d 910, 928, 148 Cal.Rptr. 389 (1978). *Neal* was reaffirmed in *Adams*.

Rule 59 does not provide any meaningful judicial scrutiny of punitive damage awards; the lack of such standards denied petitioner procedural due process of law.[21] Rule 59 provides no more post-trial scrutiny of punitive damage awards in diversity cases than did the procedures of Vermont and Mississippi about which the Justices expressed constitutional concern in *Browning-Ferris* and *Bankers Life & Casualty Co. v. Crenshaw*, 486 U.S. 71, 108 S. Ct. 1645, 100 L. Ed. 2d 62 (1988).

"The authority to grant a new trial . . . is confided almost entirely to the exercise of discretion on the part of the trial court." *Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33, 36, 66 L. Ed. 2d 193, 197, 101 S. Ct. 188, ___ (1980). Appellate review does not constrain the district court's discretion or the jury's discretion with respect to punitive damage awards because appellate review is limited to an abuse of the district court's discretion. *Fairmount Glass*

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[21] In pertinent part, Rule 59 provides: "(a) *Grounds*. A new trial may be granted to all or any of the parties and on all or part of the issue (1) in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States."

Works v. Cub Fork Coal Co., 287 U.S. 474, 77 L. Ed. 439, 53 S. Ct. 252 (1933). A district court does not abuse its discretion in upholding a punitive damage award unless the appellate court decides that the verdict was the result of passion, bias, or prejudice, or other improper motive or was so excessive as to shock the appellate judicial conscience. *E.g., Superbird Farms, Inc. v. Perdue Farms, Inc.*, 970 F.2d 238 (7th Cir. 1992); *Auster Oil & Gas, Inc. v. Stream*, 835 F.2d 597 (5th Cir. 1988); *Nairn v. National R.R. Passenger Corp.*, 837 F.2d 565 (2d Cir. 1988); *Whitely v. OKC Corp.*, 719 F.2d 1051 (10th Cir. 1983); *Community Television Services, Inc. v. Dresser Industries, Inc.*, 435 F. Supp. 214 (D.S.D. 1977), *aff'd*, 586 F.2d 637 (8th Cir. 1978); *Bonn v. Puerto Rico Int'l Airlines, Inc.*, 518 F.2d 89 (1st Cir. 1975).

This Court has relied heavily on the lengthy history of the common law relating to punitive damage awards in deciding whether punitive damage standards applied in state courts comply with due process. Common law is irrelevant in determining whether federal procedural law provides for meaningful judicial scrutiny of punitive damage awards in diversity cases for the obvious reason that the common law has nothing to say about federal procedural rules.

The plain truth is that federal judicial review of punitive damages in diversity cases provides no "definite and meaningful constraint on the discretion of [California] factfinders in awarding punitive damages." *Haslip*, 499 U.S. at 22, 113 L. Ed. 2d at 22, 111 S. Ct. at 1054. Unlike Alabama plaintiffs, California plaintiffs do "enjoy a windfall because they have the good fortune to have a defendant with a deep pocket." *Ibid.* Respondent and her lawyers have enjoyed just such a windfall.

With exceptions not here pertinent, a district court cannot overturn a jury's discretion in awarding punitive damages in diversity cases, and appellate courts must defer to the district court's discretion without exercising discretion of their own. Three levels of standardless discretion have brought to fruition the danger of which this Court warned in *Honda Motor Co.*.

E. The Circuits are in Conflict on the Application of *Haslip* to Punitive Damage Awards in Diversity Cases

No less process is due under the Fifth Amendment than under the Fourteenth Amendment. Yet, federal appellate courts have been unable to agree on the correct application of *Haslip* in diversity cases. The Fourth Circuit is in conflict with the Ninth, and the Eighth Circuit is on a different tack from either one.

In *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95 (4th Cir. 1991), the issue arose in a diversity action for personal injuries suffered in an automobile collision in South Carolina. The jury awarded the plaintiffs compensatory damages of $75,000 and punitive damages of $100,000. The district court denied post-trial motions for judgment NOV, a new trial, and a remittitur. On appeal, the defendant challenged the punitive damages award on due process grounds. Unlike Alabama, South Carolina had no post-verdict standards of review. Relying on *Haslip*, the court held that the lack of standards constraining discretion deprived defendant of due process. Contrary to the Ninth Circuit, the Fourth Circuit followed *Browning-Ferris*:

> The legitimizing constraints provided by the quasi *de novo* review process practiced under Alabama state law cannot be applied by a federal district court. While a district court must apply the substantive law of the state when instructing the jury on punitive damages, *see Erie R.R. Co. v. Tompkins*. 304 U.S. 64, 58 S. Ct. 817, 82 L. Ed. 1188 (1938), it must also apply the Federal Rules of Civil Procedure and, therefore, must review the jury verdict under standards established by Rules 50(b) (directed verdict and j.n.o.v.) and 59 (new trial). Moreover, the review by a federal district court of a jury verdict is always subject to the Seventh Amendment constraints guarantying the right to a jury trial which are not imposed on any state-prescribed post-trial review. This division in the application of substantive state law and federal procedural law is specifically confirmed in *Browning-Ferris*. . . . 947 F.2d at 99.

The South Carolina law relating to punitive damage awards closely resembles that of California. The only constraint on the award by the jury is provided by the discretion given to the district court to review the award for excessiveness.

After the case had been orally argued, but before its opinion came down, the Supreme Court of South Carolina adopted post-trial review standards similar to those in Alabama. The Fourth Circuit explained that the district court could not itself apply those standards on retrial because it had to apply Rules 50(b) and 59 of the Federal Rules of Civil Procedure. To resolve the dilemma posed by the Seventh Amendment, the Court remanded the case

to the district court with directions to instruct the jury in accordance with South Carolina's post-trial standards.

The Eighth Circuit took a different view from the Fourth in *Latham Seed Co. v. Nickerson American Plant Breeders, Inc.*, 978 F.2d 1493 (8th Cir. 1992), a diversity case, in which the plaintiff claimed damages for breach of an oral contract and for fraud invoking state law. The Eighth Circuit had earlier remanded the same case to the district court after *Haslip*; on remand, the district court reviewed the punitive damage awards by applying the post-review standards of Alabama. The district court thereafter held that the damage awards were proper, and this appeal followed.

Without addressing the question whether the district court could apply standards that had never been adopted by the state, the law of which was controlling, and without considering Rule 59, the court upheld the district court on the theory that "the district court's additional scrutiny of the award under the seven *Haslip* factors helps to ensure that the jury's verdict satisfied due process requirements." 978 F.2d at 1501.

CONCLUSION

The questions herein presented are ripe for this Court's determination. Petitioner prays that this Court will grant *certiorari* in this case.

Dated: November 10, 1994

Respectfully submitted,

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Admitted to the Bar
of the Supreme Court
on January 8, 1962

No. 94-___

In The

Supreme Court of the United States

October Term, 1994

MARIANN HOPKINS,

Plaintiff-Appellee-Respondent,

v.

DOW CORNING CORPORATION,

Defendant-Appellant-Petitioner.

APPENDIX TO PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MARIANN HOPKINS, Plaintiff-Appellee v. DOW CORNING CORPORATION, Defendant-Appellant	NO. 92-16132 D.C. No. CV-88-04703-TEH OPINION

Appeal from the United States District Court
for the Northern District of California
Thelton E. Henderson, Chief District Judge, Presiding

Argued and Submitted
June 18, 1993 – San Francisco, California

Filed August 26, 1994

Before: Donald P. Lay,* Procter Hug, Jr., and
Mary M. Schroeder, Circuit Judges.

Opinion by Judge Hug

SUMMARY

* Honorable Donald P. Lay, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

**Civil Litigation and Procedure/
Statutes of Limitation/ Torts**

The court of appeals affirmed a district court judgment. The court held that the district court correctly found that, under California's delayed discovery rule, a plaintiff's action for injuries suffered as a result of silicone breast implants was not barred by the applicable statute of limitations.

In 1976, appellee Mariann Hopkins had reconstructive surgery on her breasts. Silicone gel implants manufactured by appellant Dow Corning Corporation were utilized. Due to complications, the left implant was removed in 1976. In 1977, replacement implants, also manufactured by Dow, were inserted.

In 1979, Hopkins was diagnosed with mixed connective tissue disease (MCTD). In 1986, due to further complications from her breast implants, Hopkins underwent surgery. At that time, Hopkins' doctor discovered the implants had ruptured, and he proceeded to remove silicone gel that had escaped.

The ruptured implants were sent to Dow for analysis. In a report, Dow responded that it found no evidence to indicate that any of the damage was related to manufacture. None of Hopkins' physicians informed her that the ruptured implant could be responsible for her connective tissue disease.

In December, 1987, Hopkins learned from her mother that a possible connection between the ruptured implants and the immune disorder might exist. Hopkins' physician, however, informed her that he had never heard of such a connection. In 1988, another doctor was also

unable to provide information regarding a possible causal connection.

On December 1, 1988, Hopkins filed a diversity action against Dow, alleging fraud, strict products liability, and breach of express and implied warranties. On cross motions for summary judgment, the district court ruled that Hopkins' suit was timely filed.

Evidence presented during the liability phase of the trial indicated that Dow rushed development of the implants, failed to adequately test them, and ignored knowledge of adverse health consequences associated with them. Evidence further indicated that in addition to evidence of silicon leakage, Dow implants experienced a high rate of rupture. There was also evidence that no research concerning long-term health effects had been conducted. Other evidence indicated that Dow had knowledge of harmful effects of silicone on the human body. The district court denied Dow's motion in limine attacking the admissibility of the testimony of Hopkins' expert witnesses.

A jury returned a special verdict finding Dow liable on all of Hopkins' theories. After a second trial pertaining to damages, the jury awarded Hopkins $840,000 in compensatory damages and $6.5 million in punitive damages.

Dow appealed, contending that Hopkins' strict liability and breach of warranty claims were barred by California's one-year statute of limitations for personal injury claims. Dow also contended that the district court erred in denying its motion attacking the admissibility of Hopkins' experts' testimony. Dow further contended that an exception from strict liability for manufacturers of

prescription drugs applied. Finally, Dow also challenged the size of the damage awards.

[1] Under California's discovery rule, the accrual date of a cause of action is delayed until the plaintiff is aware of her injury and its negligent cause. [2] Hopkins pled the facts necessary to invoke the discovery rule; she alleged that prior to December 1, 1987 she never had any reason to suspect that her silicone breast implants were the wrongful cause of her MCTD; [3] in addition, deposition testimony of doctors showed that they did not inform her of the link between the implants and her disease; [4] moreover, Hopkins testified that her review of Dow's report convinced her that the implants were not defective. Facts, therefore, demonstrated Hopkins' time of discovery and further demonstrated circumstances excusing her delayed discovery.

[5] Dow failed to set forth specific facts indicating that when Hopkins first learned that the implants had ruptured in 1986, Hopkins actually suspected that she had been injured and that her injury was caused by wrongdoing. [6] In the absence of specific factual evidence, there could be no triable issue of fact as to whether Hopkins actually knew that she had been injured and that her injury was caused by wrongdoing. [7] Furthermore, Dow failed to present specific facts to create a genuine issue of material fact as to whether Hopkins should have suspected that she had been injured and that her injury was caused by wrongdoing in 1986.

[8] The uncontradicted facts demonstrated that prior to December 1987, Hopkins neither suspected nor should have suspected that she had been injured or that

any injury was caused by wrongdoing. Accordingly, the applicable statute of limitations was tolled until Hopkins' discovery in December 1987. The district court's order granting summary judgment in favor of Hopkins on this question was therefore proper.

[9] The knowledge, skill, and experience of Hopkins' experts was sufficient to qualify them as experts. [10] In addition, the "reasoning or methodology" underlying their testimony was "scientifically valid." [11] Accordingly, the district court's decision to admit the expert testimony was not an abuse of discretion.

[12] The strict liability exception for prescription drugs was inapplicable in this case. [13] The requirements for the exemption were not met; there was a failure to establish that the product was properly prepared or that the appropriate warnings were given. Thus, even if the prescription drug exemption were extended to implanted medical devices, the exemption would be inapplicable because the essential conditions of the special exemption were not met.

[14] Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award. Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, could properly be considered in imposing an award of punitive damages.

COUNSEL

Shirley M. Hufstedler, Hufstedler, Kaus & Ettinger, Los Angeles, California, for the defendant-appellant.

Laurence H. Tribe, Law Professor, Cambridge, Massachusetts, for the plaintiff-appellee.

OPINION

HUG, Circuit Judge:

In this diversity action, Mariann Hopkins sued Dow Corning Corporation to recover for injuries suffered as a result of two sets of breast implants manufactured by Dow, which she received in breast reconstruction surgeries in 1977 and 1986. The jury found Dow liable for Hopkins' injuries and awarded Hopkins $840,000 in compensatory damages and $6.5 million in punitive damages. Dow appeals.

Dow contends that the district court erred in determining that Hopkins' claims were not barred by the applicable statute of limitations. Dow challenges the district court's determination that the evidence presented at trial was sufficient to support a finding of fraud and further challenges the court's decision to admit the plaintiff's expert testimony on the issue of causation. Finally, Dow challenges the amount of both the compensatory and the punitive damages awards.

The district court's jurisdiction was based upon 28 U.S.C. § 1332(a)(1). We exercise jurisdiction over this timely appeal pursuant to 28 U.S.C. § 1291. We affirm.

I. FACTS

On October 4, 1976, plaintiff Mariann Hopkins underwent a bilateral subcutaneous mastectomy for severe fibrocystic disease at St. Mary's Hospital in San Francisco, California. Dr. Karl Bollinger performed the surgery. During the operation, Dr. Bollinger performed reconstructive surgery on plaintiff's breasts utilizing silicone gel implants manufactured by defendant Dow Corning.

Due to subsequent complications, Dr. Bollinger removed the left implant in November, 1976. In June, 1977, Dr. Bollinger inserted a replacement implant in the left breast and replaced the right breast implant in order to achieve symmetry. These implants were also manufactured by the defendant.

In March, 1979, Dr. Stephen Gospe diagnosed plaintiff with mixed connective tissue disease ("MCTD"). MCTD is a rheumatological disorder which includes symptoms such as extreme fatigue, weakness, muscle aches and pains, arthralgia, myalgia and arthritis. There is no known cure for this disease.

In January, 1986, plaintiff contacted Dr. Bollinger about further complications from her breast implants. Plaintiff underwent surgery in February to correct the problem. At that time, Dr. Bollinger discovered the implants had ruptured; during the four-hour operation, he proceeded to remove silicone gel that had escaped from the implant. The ruptured implants were sent to Dow for analysis. Several months later, Dow responded to Dr. Bollinger that "examination and testing of both

envelopes found no evidence to indicate that any of the damage was manufacture related." Dr. Bollinger informed plaintiff of these results.

None of plaintiff's physicians informed her that the ruptured implant could be responsible for the connective tissue disease from which she suffered. In December, 1987, plaintiff learned from her mother that a possible connection between the ruptured implants and the immune disorder might exist. Shortly thereafter, plaintiff inquired of her physician, Dr. Pelfini, if a possible causal link existed. Dr. Pelfini informed plaintiff that he had never heard of such a connection. In January, 1988, plaintiff visited another of her treating physicians, Dr. Gospe, and inquired the same of him. Dr. Gospe was also unable to provide information regarding a possible causal connection. Plaintiff filed her complaint on December 1, 1988, alleging fraud, strict products liability and breach of express and implied warranties, and requesting compensatory and punitive damages.

The case was bifurcated so that issues regarding liability would be determined first, and if needed, a second trial on damages would be held. The liability phase of the trial began on October 29, 1991. The evidence presented at trial indicated that Dow rushed development of the silicone gel implants, failed to adequately test the implants, and ignored knowledge of adverse health consequences associated with the implants. Plaintiff presented evidence that Dow created a Mammary Task Force charged with getting the new gel implant to market in less than five months. Even after a task force member presented his concerns about "a possible gel bleed situation" Dow ignored proposed design modifications that

would reduce the likelihood of leakage. The record indicates that Dow instructed salesmen to wash the implants with "soap and water" in the nearest rest room, and to "dry with hand towels as the implants become oily after being handled and [bleed] on the velvet in the showcase."

The evidence further indicated that in addition to the evidence of silicone leakage, Dow implants experienced a high rate of rupture. Despite proposals by one task force member to implement a "multiple dip" method as a means of ensuring greater uniformity in the envelope, and thereby less likelihood of rupture, Dow adopted the single dip method because it was "easier" and "cheaper." After an incident in which two of the new gel implants "broke during augmentation surgery for the TV taped demonstrations," Thomas Talcott, a Dow engineer, inquired of key Dow employees, "When will we learn at Dow Corning that making a product 'just good enough' almost always leads to products that are 'not quite good enough?' "

There was also evidence that no research concerning the long-term health effects had been conducted. The longest study to address possible adverse health effects of the implants took place over only 80 days and revealed evidence of inflammatory immune response caused by the gel. Dow continued to market these implants until 1987, without the benefit of a lifetime study to demonstrate the safety of its product.

Other evidence at trial indicated that Dow had knowledge of the harmful effects of silicone on the human body. Dow obtained results of a study in which four dogs received silicone gel implants that resembled

the implants that Dow was then marketing. The results demonstrated that after six months, the implants appeared to be functioning properly, but that after two years, inflammation surrounding the implants demonstrated the existence of an immune reaction. Dow did not publicly release the results of this research for several years, and when it did ultimately release the results, Dow omitted the negative findings and implied that the implants were safe.

Based on these facts, the jury returned a special verdict finding the defendant liable on all plaintiff's theories, including strict liability, breach of warranty, and fraud. The second trial, pertaining to the amount of damages, began on December 11, 1991. The jury awarded plaintiff $840,000 in compensatory damages and $6.5 million in punitive damages. The district court denied Dow's motion for a directed verdict. The district court also denied Dow's motions for judgment notwithstanding the verdicts and, alternatively, a new trial. Dow appealed.

II. STATUTE OF LIMITATIONS

Dow contends that Hopkins' strict liability and breach of warranty claims are barred by California's one-year statute of limitations for personal injury claims. Hopkins asserts that her claims were timely because they were filed pursuant to the "delayed discovery" doctrine.

[1] Hopkins and Dow agree that California Code of Civil Procedure § 340(3), which sets forth a one-year statute of limitations period for "an action . . . for injury to . . . one caused by the wrongful act or neglect of another," applies to the products liability and breach of

warranty theories alleged in this case. The parties also agree that the common law rule, which provides that a cause of action accrues on the date of the injury, applies except as modified by the discovery rule. Under California's discovery rule, the accrual date of a cause of action is delayed until the plaintiff is aware of her injury and its negligent cause. *Jolly v. Eli Lilly & Co.*, 751 P.2d 923, 926-27 (Cal. 1988); *Frederick v. Calbio Pharmaceuticals*, 152 Cal.Rptr. 292, 294 (Ct. App. 1979). The parties disagree as to when Hopkins became aware of her injury and its wrongful cause and, thus, whether Hopkins initiated this action in a timely manner.

On cross motions for summary judgment, the district court ruled that Hopkins' suit was timely filed.[1] We review *de novo* the district court's determinations on summary judgment. *Jones v. Union Pac. R.R. Co.*, 968 F.2d 937, 940 (9th Cir. 1992); *T.W. Elec. Serv., Inc. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 629 (9th Cir. 1987). We must determine whether there are any genuine issues of material fact and whether the district court correctly applied the relevant substantive law. *Federal Deposit Ins. Corp. v. O'Melveny & Myers*, 969 F.2d 744, 747 (9th Cir. 1992), *cert. granted*, 114 S. Ct. 543 (U.S. Nov. 29, 1993); *Tzung v. State Farm Fire and Casualty Co.*, 873 F.2d 1338, 1339-40 (9th Cir. 1989).

Under California's discovery rule, "the statute of limitations begins to run when the plaintiff suspects or

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[1] In its motion for summary judgment, Dow argued that all of Hopkins' claims, except those based upon fraud and negligent misrepresentation, were time-barred.

should suspect that her injury was caused by wrongdoing, that someone has done something wrong to her." *Jolly*, 751 P.2d at 927. Plaintiff need not know the specific facts necessary to establish her claim. *Id.* at 928. Once plaintiff has " 'notice or information of circumstances to put a reasonable person on inquiry, or has the opportunity to obtain knowledge from sources open to [her] investigation, . . . the statute commences to run' " *Braxton-Secret v. A.H. Robins Co.*, 769 F.2d 528, 530 (9th Cir. 1985) (citation omitted). To invoke the discovery rule, plaintiff must plead facts which show "(1) the time and manner of discovery and (2) the inability to have made earlier discovery despite reasonable diligence." *Saliter v. Pierce Bros. Mortuaries*, 146 Cal.Rptr. 271, 274 (Ct. App. 1978) (citing *G.D. Searle & Co. v. Superior Court*, 122 Cal.Rptr. 218, 220 (Ct. App. 1975)).

[2] Hopkins pled the facts necessary to invoke the discovery rule. With respect to the time and manner of her discovery that her injury may have been caused by wrongdoing, Hopkins alleged in her complaint that prior to December 1, 1987, plaintiff never had any reason to suspect that her silicone breast implants were the wrongful cause of her MCTD.

In ruling on the cross motions for summary judgment, the district court granted Hopkins' motion and denied Dow's. Dow appeals both orders. Obviously, if Hopkins' motion was properly granted, Dow's was properly denied. We therefore initially consider the order granting Hopkins' summary judgment.

A party seeking summary judgment bears the initial burden of informing the district court of the basis for its

motion, identifying those portions of its pleadings, depositions, answers to interrogatories, admissions on file or affidavits that demonstrate an absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A dispute as to a material fact is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Hopkins concedes that she would have the burden of proof at trial that her discovery of the wrongdoing was within one year from the time she filed her action. Thus, in order to prevail on the motion for summary judgment, she had to show that Dow failed to present evidence sufficient to create a genuine issue of fact as to whether the action was filed within one year of the discovery of the wrongdoing. *See Celotex*, 477 U.S. at 322. The standard for granting a summary judgment is equivalent to the standard for granting a judgment as a matter of law under Fed. R. Civ. P. 50. *Id.* at 323.

[3] In her deposition, Hopkins testified that she learned of the possible connection between breast implants and autoimmune disease from her mother in December, 1987.[2] Thereafter, Hopkins asked Drs. Pelfini and Gospe about the possible connection. Like Dr. Bollinger's deposition testimony, the deposition testimony of Drs. Pelfini and Gospe shows that neither was aware of

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[2] The record does not reflect the circumstances surrounding Hopkins' mother's knowledge of the possible connection between MCTD and the breast implants, nor does the record suggest that Hopkins' mother learned of the connection prior to December, 1987.

or informed her of the link between the implants and her disease. Hopkins also testified that she had never read any news report or other article in any newspaper or magazine about the possible link between breast implants and autoimmune disease. Hopkins filed her complaint on December 1, 1988, within one year of her alleged discovery in December, 1987.

[4] With respect to the circumstances excusing delayed discovery, Hopkins asserted that when she first learned that the implants had ruptured in February, 1986, she had no reason to suspect that the rupture had caused her injury or that any injury was the result of wrongdoing. Hopkins testified that her review of Dow's Complaint Analysis Report convinced her that the implants were "not defective in any way." The report made no mention of medical research indicating a link between silicone and MCTD. Moreover, the report stated, as to both implants, that (1) "[t]he envelope displayed no abnormality in the area of the rupture" and (2) "[t]he thickness [of the implant envelope] is within the product specification limits." The report concluded that "[e]xamination and testing of both envelopes found no evidence to indicate that any of the damage was manufacture related." In response to requested discovery, Dow admitted that the report "does not state that the implants were defective in design" and "does not state that breast implants may rupture without cause following implantation." We conclude that these facts demonstrate Hopkins' time of discovery, and further demonstrate circumstances excusing her delayed discovery.

We must next consider whether Dow set forth specific facts sufficient to demonstrate the existence of a genuine issue of material fact for trial regarding the discovery rule. In reviewing an order granting summary judgment, we are limited to the facts shown in the affidavits, depositions, interrogatories, admissions, uncontested pleadings, and other evidence available to the court at the time the motion was made. *Jewel Companies v. Pay Less Drug Stores Northwest*, 741 F.2d 1555, 1559 (9th Cir. 1984).[3]

Dow contends that the statute started running in 1986 when Dr. Bollinger discovered the ruptured implants during the February, 1986 surgery, and that Hopkins was responsible for investigating the possibility of wrongdoing at that time. The injury for which Hopkins seeks recovery is the MCTD, which she contends was caused by the defective implants. Dow maintains that Hopkins manifested suspicion of wrongdoing by asking for Dow's laboratory analysis of the returned implants and, therefore, that she was obligated to undertake an investigation into the possibility of wrongdoing. Dow submits that a simple investigation would have revealed

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[3] An order granting summary judgment governs the future course of the trial, with the parties having considered the issue to be settled. This is to be distinguished from an order denying summary judgment, where the parties anticipate the production of further evidence on the issue of fact and may respond at trial. In that circumstance, the adequacy of the evidence to justify a jury's consideration of the issue is properly considered in the context of a motion for a judgment as a matter of law under Fed. R. Civ. P. 50. *See Stuckey v. Northern Propane Gas Co.*, 874 F.2d 1563, 1567 (11th Cir. 1989).

to Hopkins the possible connection between the implants and MCTD.

[5] We conclude that Dow failed to set forth specific facts indicating that when Hopkins first learned that the implants had ruptured in February, 1986, Hopkins actually suspected that she had been injured and that her injury was caused by wrongdoing. Dow did not point to any medical or testimonial evidence demonstrating that Hopkins was actually suspicious. Unlike the plaintiff in *Jolly*, Hopkins never stated that "she was interested in 'obtaining more information' about [the implants] because she wanted to 'make a claim;' she felt that someone had done something wrong to her concerning [the implants], that [they were] defective [prostheses] and that she should be compensated." *Jolly*, 751, P.2d at 929. Hopkins' statements were simple inquiries and not reflective of any suspicion of wrongdoing by Dow.

[6] The statements Hopkins made are contrary to those made in *Jolly* and are readily distinguishable from those made by the plaintiffs in the cases on which Dow relies. *See Miller*, 2 Cal. Rptr. 2d at 803 (on summary judgment, plaintiff expressly agreed that it was undisputed that the letter, which her husband sent to defendant almost two years before she filed her complaint, stated that the flooding caused mold which caused her injuries); *Gutierrez v. Mofid*, 705 P.2d 886, 888-89 (Cal. 1985) (the evidence on summary judgment made clear, and plaintiff conceded for purposes of argument, that she both knew of her injury and suspected malpractice almost immediately after the operation – almost two years before she filed suit); *Snow v. A.H. Robins Co., Inc.*,

211 Cal.Rptr. 271, 275 (Ct. App. 1985) (plaintiff's deposition testimony demonstrated that eight years prior to filing her complaint, she viewed the Dalkon Shield as responsible for her ultimate injuries); *Sidney-Vinstein v. A.H. Robins Co.*, 697 F.2d 880, 884 (9th Cir. 1983) (plaintiff testified at her deposition that she understood immediately after the hysterectomy, more than six years before she filed suit, that the Dalkon Shield had not done what it was supposed to do and that it had caused the infection). There has been no evidence presented that Hopkins ever made statements of this nature. In the absence of specific factual evidence, there can be no triable issue of fact as to whether Hopkins actually knew that she had been injured and that her injury was caused by wrongdoing.

[7] Furthermore, we also conclude that Dow failed to present specific facts to create a genuine issue of material fact as to whether Hopkins should have suspected that she had been injured and that her injury was caused by wrongdoing in February, 1986. Unlike the Dalkon Shield cases cited by Dow, this is not a case in which the only reasonable conclusion that Hopkins could have drawn was that the failure of the medical device to serve its purpose was the possible cause of her injury. *See Braxton-Secret*, 769 F.2d at 531 ("When she discovered, after suffering a miscarriage, that she had been pregnant while the IUD was still in place, the only reasonable conclusion she could have drawn was that the IUD failed its contraceptive purpose" and caused her pregnancy and incomplete spontaneous abortion); *Snow*, 211 Cal.Rptr. at 276 ("An abortion is an event sufficient to alert a victim

of unwanted pregnancy while using an IUD 'to the necessity for investigation and pursuit of her remedies.' ") (citation omitted).

Hopkins' case is drastically different from the Dalkon Shield cases discussed above. It is widely known that an intra-uterine device, like any contraceptive, is designed to prevent pregnancy. Further, it is commonly understood that there is a direct connection between contraceptives and pregnancy. In contrast, the purpose of breast implants is not to prevent autoimmune disease, and it is not commonly understood that there is any connection, let alone a direct connection, between breast implants and MCTD. The Dalkon Shield cases are simply inapposite.

Dow contends that if Hopkins had undertaken a simple investigation, she would have discovered the possible link between breast implants and MCTD. We reject this contention. Hopkins' review of Dow's Complaint Analysis Report certainly did not reveal to her the possible connection; the report made no mention of medical research indicating a link between silicone and autoimmune diseases. Further, Hopkins, a lay person, was unlikely to discover the single article from a professional medical journal[4] and two cases like Hopkins' case against Dow, which Dow identified in its moving papers. Unlike *Jolly*, this is not a case in which "a timely investigation

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[4] Dow identified an article entitled, "Human Adjuvant Disease, Possible Autoimmune Disease After Silicone Implantation: A Review of the Literature." The article appeared in the July, 1986 edition of *Plastic and Reconstructive Surgery*, a periodical published by the American Society of Plastic and Reconstructive Surgeons.

would have disclosed numerous articles concerning [the possible link between breast implants and autoimmune disease] [in lay publications] and many [breast implants] suits filed throughout the country alleging wrongdoing." *Jolly*, 751 P.2d at 929. As the district court accurately observed, the article and lawsuits cited by Dow were neither numerous nor notorious enough to put Hopkins on notice about her injury.

Any information that a "simple investigation" arguably would have revealed to Hopkins should have come from Dow itself. In responses to requests for admissions, Dow stated that there were "reports in the published medical literature of suspected immunological sensitization or hyperimmune system response to silicone mammary implants" as of May, 1986. However, Dow neglected to mention this association in its Complaint Analysis Report so that Hopkins could take appropriate action. Instead, Dow elected to suppress this information. A simple investigation would not have revealed the existence of this information, and none of Hopkins' physicians answered her questions with any information suggesting that such a link existed. We agree with the district court that "the Complaint Analysis Report issued by Dow encouraged, if not created, plaintiff's belief that defendant's product was not defective and that she was not injured" such that "[r]uling in defendant's favor here would therefore unjustly reward defendant for misleading consumers such as Ms. Hopkins." We conclude that any effort by Hopkins to determine whether there was wrongdoing or whether there existed a possible link between breast implants and autoimmune disease were

hampered by Dow, and that Hopkins' eventual discovery was made in spite of Dow.

[8] The uncontradicted facts presented in support of the motions for summary judgment demonstrate that prior to December, 1987, Hopkins neither suspected nor should have suspected that she had been injured or that any injury was caused by wrongdoing. Accordingly, we conclude that the applicable statute of limitations was tolled until Hopkins' discovery in December, 1987, and the district court's order granting summary judgment in favor of Hopkins on this question was proper.

III. ADMISSIBILITY OF EXPERT WITNESS TESTIMONY

Dow argues that the district court erred in denying Dow's motion in limine attacking the admissibility of the testimony of Hopkins' three expert witnesses. Dow maintains that the testimony on the issue of causation should have been excluded because it was not based on scientifically accepted standards. Further, Dow asserts that without the expert testimony, Hopkins would have been unable to satisfy her burden of proving that the implants caused her injuries. We review a district court's evidentiary rulings for abuse of discretion. *Roberts v. College of the Desert*, 870 F.2d 1411, 1418 (9th Cir. 1988).

When confronted with an offer of expert testimony, the trial judge must first determine, pursuant to Rule 104(a) and Rule 702, whether the expert is proposing to testify to scientific knowledge that will assist the trier of

fact in resolving a fact in issue.[5] Dow asserts that the district court erred in not holding a formal hearing. We disagree. The district court is not required to hold a Rule 104(a) hearing, but rather must merely make a determination as to the proposed expert's qualifications.

[9] Dow objects to the admission of testimony from Hopkins' three expert witnesses: Drs. Lappe, Kossovsky and Vasey. Dow asserts that Dr. Lappe was not qualified to testify as an expert because he was not qualified to recount a causal connection between Hopkins' implants and the disease from which she suffered. Hopkins contends that although Lappe is not a medical doctor, he is a nationally-renowned toxicologist who has served federal and state agencies as well as private organizations in determining the safety of substances and materials for use by human beings. With respect to Drs. Kossovksy and Vasey, Dow asserts that although they were medical doctors qualified to diagnose the cause of illness, neither was

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[5] Federal Rule of Evidence 104(a) provides:

> (a) Preliminary Questions of admissibility generally. Preliminary questions concerning the qualification of a person to be a witness, the existence of a privilege, or the admissibility of evidence shall be determined by the court, subject to the provisions of subdivision (b). In making its determination, it is not bound by the rules of evidence except those with respect to privileges.

Federal Rule of Evidence 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

qualified to testify to Hopkins' condition because neither had examined her. We conclude that the knowledge, skill, and experience of Hopkins' three experts was sufficient to qualify them as experts within the meaning of Rule 104(a). The district court's decisions were proper.

Dow further challenges the admissibility of Hopkins' experts' testimony on the basis that the experts' methodology was not based on generally accepted scientific principles. The admission of such expert testimony is controlled by *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2796 & n.11 (1993). In *Daubert*, the Supreme Court held that the *Frye* "general acceptance" test was superceded by the adoption of the Federal Rules of Evidence. 113 S. Ct. at 2793. Focusing on the history of Rule 702, the Court stated, "[t]he drafting history makes no mention of *Frye*, and a rigid 'general acceptance' requirement would be at odds with the 'liberal thrust' of the Federal Rules and their 'general approach of relaxing the traditional barriers to 'opinion' testimony.' " *Id.* at 2794 (citing *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)). In formulating an approach to Rule 702, the Court noted that the trial judge must ensure that any scientific testimony or evidence ultimately admitted is "not only relevant, but reliable." *Id.* at 2795. The Court stated that the expert's testimony must be based on "scientific . . . knowledge," implying a "grounding in the methods and procedures of science" and must connote "more than subjective belief or unsupported speculation." *Id.* The inquiry is to be a flexible one, and "must be solely on principles and methodology, not on the conclusions that they generate." *Id.* at 2797.

Thus, according to *Daubert* and Rule 702, the testimony of these experts need not be based on "generally accepted" methodologies, but rather must be based on "scientific knowledge" that will "assist the trier of fact." *Id.* at 2794, 2795; Fed. R. Evid. 702. The record reflects that Hopkins' experts based their opinions on the types of scientific data and utilized the types of scientific techniques relied upon by medical experts in making determinations regarding toxic causation where there is no solid body of epidemiological data to review. The record demonstrates that Dr. Lappe is a recognized expert on the immunological effects of silicone in the human body. Specifically, Dr. Lappe testified that his opinion was based on his experience as a toxicologist, his review of medical records and Dow studies, and his general scientific knowledge of silicone's ability to cause immune disorders as established by animal studies and biophysical data.

Another of Hopkins' experts, Dr. Kossovsky, testified that the methodology used by Hopkins' experts in reaching their conclusions dated back to 1976. Specifically, he testified that his opinion was based on scientific studies he authored, his participation in a preliminary epidemiological study involving over 200 women, and his examination of Hopkins during which he discovered evidence of silicone in her tissue and detected symptoms consistent with exposure to silicone. He also testified to the presence of corroborating evidence found in studies conducted on animals.

[10] Dr. Vasey, a rheumatologist, testified that his opinion was based on medical records, his clinical experience, preliminary results of an epidemiological study and

medical literature. Thus, we conclude the "reasoning or methodology underlying the testimony is scientifically valid. . . . " *Daubert*, 113 S. Ct. at 2796.

[11] We conclude that Hopkins' experts' opinions were based on scientific techniques that satisfied the requirements established in *Daubert*. Accordingly, the district court's decision to admit the expert testimony was not an abuse of discretion.

IV. STRICT LIABILITY

Dow asserts that the district court erred in denying its motion in limine regarding the exemption from strict liability on the basis of comment K of the Restatement of Torts and the line of California cases which have followed its reasoning. Hopkins maintains that the exemption from strict liability provided by comment K has no applicability to the facts of this case. We agree with Hopkins that the claimed exception for manufacturers of prescription drugs is unavailable to Dow.

Comment K provides as follows:

> k. *Unavoidably unsafe product.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to

> physicians or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability. . . .

In *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988), the California Supreme Court adopted this approach in exempting the manufacturers of prescription drugs from strict liability for injuries caused by their products. Earlier California cases which addressed the applicability of comment K to prescription drug cases have required that the drug at issue be found to be "unavoidably dangerous." The *Brown* decision, however, disavowed this requirement and concluded that the comment K exception was intended to apply to all prescription drugs, not merely those which have been found to be "unavoidably dangerous." *Id.* at 482. In reaching this conclusion, the *Brown* court articulated numerous policy justifications for exempting such manufacturers from strict liability, particularly the importance of developing pharmaceutical products designed to alleviate pain and suffering. In light of these overriding public policy concerns, the *Brown* court concluded that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known

or reasonably scientifically knowable at the time of distribution." *Id.* at 482-83.

[12] Dow contends that under California law the exception for prescription drugs extends to the implants placed in Hopkins' body. It relies on a California Court of Appeal case that extends this exception to implant medical devices. *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377 (Ct. App. 1992). We need not consider whether this extension of the exception would be adopted by the California Supreme Court because we conclude the exception is inapplicable to the facts of this case.

[13] In the present case, the jury returned special verdicts, finding (1) that the mammary implant was defectively designed, (2) that it was defectively manufactured, and (3) that Dow failed to warn of a known or knowable risk of harm of the type the plaintiff alleged occurred to her. These findings were adequately supported by substantial evidence. Because of these jury findings, it is clear that the requirements for the exemption to strict liability announced in *Brown* for prescription drugs were not met. There was a failure to establish that the product was properly prepared or that the appropriate warnings were given. Thus, even if this prescription drug exemption were extended to implanted medical devices, the exemption would be inapplicable because the essential conditions of the special exemption were not met.

Because there was adequate evidence to sustain the jury's finding of liability on the basis of strict liability, we need not consider the other theories of liability.

V. THE DAMAGE AWARD

Hopkins was awarded $840,000 in compensatory damages and $6.5 million in punitive damages. Dow challenges the size of these awards. Dow contends that the compensatory damage award vastly exceeds actual damages sustained and further contends that the punitive damages award cannot be sustained because it is "grossly excessive," and no understandable relationship exists between actual damages and punitive damages. Hopkins asserts that the record contains ample evidence to support the amount of both the compensatory and the punitive damage awards.

A. *Compensatory Damages*

The record indicates that expert testimony presented at trial supported a finding that plaintiff had lost $404,083 in earnings as a result of her autoimmune disease. Her past medical bills were stipulated to be $37,318 and her future medical bills were computed to a present value of $31,600. Therefore, Hopkins' out-of-pocket losses amounted to $473,001. In addition, the jury apparently awarded Hopkins $366,999 in damages for "severe shock to the mental system" and mental pain. Other than a generalized allegation that Hopkins could not have suffered this degree of loss based on her claims, Dow offers no evidence to support its contention that the damages award was excessive. We conclude that the award of compensatory damages was proper.

B. *Punitive Damages*

"In reviewing an award of punitive damages, the role of the district court is to determine whether the jury's verdict is within the confines set by state law, and to determine, by reference to federal standards developed under Rule 59, whether a new trial or remittitur should be ordered. The court of appeals should then review the district court's determination under an abuse-of-discretion standard." *Browning-Ferris Indus. v. Kelco Disposal, Inc.*, 492 U.S. 257, 279 (1989); *see also Bouman v. Block*, 940 F.2d 1211, 1234 (9th Cir.), *cert. denied*, 112 S. Ct. 640 (1991) (trial court has discretion to award punitive damages); *Kennedy v. Los Angeles Police Dept.*, 901 F.2d 702, 707 n.3 (9th Cir. 1989) (jury has considerable discretion to award punitive damages, and its award, if supportable, will not be lightly disturbed).

The Supreme Court stated that the following considerations are relevant to a determination of whether a punitive damages award is excessive or inadequate.

> (a) whether there is a reasonable relationship between the punitive damages award and the harm likely to result from the defendant's conduct as well as the harm that actually has occurred; (b) the degree of reprehensibility of the defendant's conduct, the duration of that conduct, the defendant's awareness, any concealment, and the existence and frequency of similar past conduct; (c) the profitability to the defendant of the wrongful conduct and the desirability of removing that profit and of having the defendant also sustain a loss; (d) the "financial position" of the defendant; (e) all the costs of litigation; (f) the imposition of criminal

> sanctions on the defendant for its conduct, these to be taken in mitigation; and (g) the existence of other civil awards against the defendant for the same conduct, these also to be taken in mitigation.

Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 21-22 (1991). Application of these standards in *Haslip* imposed a sufficiently definite and meaningful constraint on the discretion of fact-finders in awarding punitive damages. *Id.*

The Supreme Court recently provided additional guidance on the issue of excessiveness of punitive damages awards in *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711 (1993) (plurality). In upholding a judgment of $19,000 in actual damages and $10 million in punitive damages, the Court opined that punitive damages awards are "the product of numerous, and sometimes intangible, factors; a jury imposing a punitive damages award must make a qualitative assessment based on a host of facts and circumstances unique to the particular case before it." *Id.* at 2720. The Supreme Court identified various principles that may be considered when reviewing a punitive damages award. For instance, a court is not limited to considering the proportionality of the punitive award to actual damages sustained, but may also consider the magnitude of the harm that potentially could have occurred and the potential gain to the defendant. The Court noted that punitive damages had been awarded by an impartial jury, as a result of collective deliberations based on arguments of adversaries and evidence, and then reviewed by the trial judge and upheld by the unanimous decision of the State Supreme Court of Appeals, "is entitled to a strong presumption of validity."

Id. at 2719-20. Under these circumstances, the judgment of the Court declined to adopt a bright line test for evaluating the constitutionality of punitive damages awards and reiterated its position in *Haslip* that a "general concer[n] of reasonableness . . . properly enter[s] into the constitutional calculus." *Id.* at 2720 (citing *Haslip*, 499 U.S. at 18). The Court indicated that while proportionality to actual damages sustained is relevant in the analysis, it is the only one of several factors to be considered. *Id.* at 2722.

[14] The evidence presented at trial established that a large number of Dow silicone gel breast implants had been implanted in thousands of women. Each of these women was at risk of encountering the same fate from which Hopkins suffered. Therefore, Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, may properly be considered in imposing an award of punitive damages. Moreover, given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive damages award is justified. Coupled with the facts that Dow is a wealthy corporation and that Dow made a considerable amount of money from the sale of its implants, the jury's award of $6.5 million is reasonable in light of *TXO* and *Haslip*. Therefore, we conclude that Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award.

VI. CONCLUSION

We conclude that the district court properly granted Hopkins' motion for summary judgment on the statute of limitations question. We further conclude that the district court properly admitted expert testimony regarding the cause of plaintiff's injuries and the award of damages is therefore upheld.

AFFIRMED.

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

MARIANN HOPKINS, Plaintiff, v. DOW CORNING, Defendant.	NO. C 88 4703 TEH (JSB) ORDER DENYING DEFENDANT'S MOTION FOR NEW TRIAL OR, IN THE ALTERNATIVE, FOR JUDGMENT NOTWITHSTANDING THE VERDICT

This matter comes before the Court on defendant's motion for a new trial or, in the alternative, for judgment notwithstanding the verdict. Oral argument was heard in this matter on April 27, 1992. Frank Woodside and Jack McGowan appeared for defendant. Charles Louderback and Dan Bolton appeared for plaintiff.

BACKGROUND

This is a personal injury case brought by plaintiff Mariann Hopkins seeking recovery for injuries she received from defective Dow silicone breast implants. We held a nine week (bifurcated) jury trial in this case which culminated on December 13, 1991 when the jury found for Ms. Hopkins on all counts and awarded her $7.3 million in compensatory and punitive damages.

Defendant Dow Corning Corporation now moves for judgment notwithstanding the verdict, or in the alternative, for a new trial. These motions are based on five separate grounds. We issued rulings from the bench denying these motions in the April 27, 1992 hearing. This order is to memorialize those rulings.

DISCUSSION

A. FRCP Rule 59(b)

Dow Corning argues that it is entitled to a new trial under FRCP Rule 59(b) because the jury's verdict on causation was against the clear weight of the evidence and was the result of conjecture, confusion and sympathy.

We ruled on this issue during the course of the trial. After reviewing defendant's arguments at this juncture, we remain convinced that they are without merit. The jury found that there was causation between the silicone breast implants and the harm suffered by Ms. Hopkins. A review of the trial record indicates that there was more than enough evidence introduced to support this finding. This evidence was provided by three witnesses: Dr. Marc Lappe, Dr. Nir Kossovsky, and Dr. Frank Vasey. Each stated in unequivocal terms that it was his expert opinion that Ms. Hopkins' MCTD was the result of the silicone in her system.

On the basis of the evidence presented by both the plaintiff and the defendant in this case, we find that there was sufficient evidence for the jury to find for plaintiff on the issue of causation. Accordingly, defendant's motion for new trial is **DENIED.**

B. Inconsistency with Our Jan. 5, 1990 Order

Defendant argues that we erred in "admitting, over defendant's objection, evidence which was factually inconsistent with the fact determined by the Court's partial summary judgment order on the statute of limitations and legally inconsistent with the premises of that order."

In 1989, we entertained, from both parties, motions for summary judgment on the question of the statute of limitations. In an order dated Jan. 5, 1990, we granted plaintiff's motion, implicitly denying that of defendant.

Defendant argues that our order granting plaintiff's motion for summary judgment was based on 4 factual suppositions:

1. The *only* injuries for which plaintiff sought recovery were injuries derived from her Mixed Connective Tissue Disease (MCTD).

2. That, as a consequence of "Supposition 1, the only "discovery" which could trigger the running of the statute of limitations on any claim was discovery of the alleged relationship between the implants and the MCTD."

3. That defendant made no disclosure to plaintiff or her doctor of any information concerning reports of association between the breast implants and immunological sensitization or hyperimmune system response, such that plaintiff was unable to discover this association until less than a year before she sued.

4. That plaintiff believed the analysis that Dow Corning made of the implants which were removed from her

person in February 1986, which analysis reported discovery of no manufacturing defect in such implants, notwithstanding the fact that they ruptured.

Defendant argues that we accepted each of these suppositions as uncontroverted in deciding the summary judgment motion and that these same suppositions must bind plaintiff at trial.

Defendant misreads our Jan. 5, 1990 order. The critical point of that order is that Ms. Hopkins' action was not barred by the statute of limitations. We did not limit the injuries for which she could obtain recovery as defendant now contends. In her original complaint, plaintiff sought recovery for all actionable injuries which resulted from the defective breast implants. Defendant, here, tries to attribute positions to plaintiff which were not taken at the time that the summary judgment motion was decided.

We find no discrepancy between the positions taken by plaintiff in her statute of limitations order and her subsequent positions at trial. Therefore, defendant's motion for a new trial on this basis is **DENIED**.

C. Special Verdict Form

During the trial, defendant objected to the special verdict form submitted to the jury. We overruled the objection after careful consideration. Defendant now argues that we erred in overruling its objection to the failure of the special verdict slip to specify the jury's unanimous findings regarding the particular injuries for which defendant was held liable. Defendant asks us to grant a new trial on that basis.

Defendant's argument is that the verdict form that we submitted did not permit the jury to distinguish between the various injuries that the plaintiff alleged. In other words, the jury spoke on whether the silicone caused the plaintiff's injuries, but was not able to say, "the silicone caused Ms. Hopkins' MCTD, but not her ulcer." The verdict form limited the jury to finding causation for all of plaintiff's injuries, or for none of them.

The standard by which to measure the adequacy of a special verdict form is whether the questions asked are "adequate to obtain a jury determination of the factual issues essential to the judgment." *In re: Hawaii Federal Asbestos Cases*, 871 F.2d 891, 894 (9th Cir. 1991).

This was a bifurcated trial. In the liability phase, the issues essential to the judgment were whether the defendant acted in a tortious manner, and if so, whether this tortious conduct resulted in damage to the plaintiff. The exact kind and extent of the damages is to be determined during the damages section of the trial. Here, the jury was allowed to answer the operative question, did Dow's conduct result in sufficient damage to the plaintiff to establish *liability*. The jury answered that question affirmatively.

The special verdict form submitted in this case was adequate. For this reason, this motion for a new trial is **DENIED**.

D. Fraud Claim Re: 1986 Implants

Defendant argues that we committed error in submitting to the jury, plaintiff's claim of fraud with respect to the 1986 implants which were removed in 1991. Defendant presented the same question in a motion *in limine*. That motion was denied.

Defendant's argument is based on the fact that the implants which were implanted in 1986 and removed in 1991 were not found to be defective. Defendant contends that the trial produced no evidence of fraud with respect to the 1986 inserts and, alternatively, that we committed error in admitting any evidence regarding these inserts since they had not ruptured. According to defendant, we also committed error in that we allowed the plaintiff to argue to the jury her case of fraud with respect to these 1986 inserts.

Under the principles of California law, as articulated in *Kahn v. Shiley, Inc.* 217 Cal. App. 3d 848 (1990), a plaintiff may prove fraud with respect to a medical device, even where that device does not malfunction. In order to prove such a claim, a plaintiff must show that a manufacturer concealed material product information from potential users.

We find that in this case, plaintiff produced sufficient evidence that defendant concealed material product information to submit the question to the jury for determination. This being the case, defendant's motion for a new trial because we erred in submitting to the jury, plaintiff's claim of fraud with respect to the 1986 implants which were removed in 1991 is **DENIED**.

E. Punitive Damages

Defendant argues that the court erred in submitting to the jury, plaintiff's claim for punitive damages, or in the alternative, that the punitive damages that were awarded were excessive. Defendant asks us to enter judgment notwithstanding the verdict on this issue, or to grant a new trial unless plaintiff agrees to a remittitur.

Defendant's motion has two bases: Dow's prior exposure to an adverse punitive damages judgment and Dow's view that the damages awarded in this case were excessive. We have addressed the first of these bases several times in the past. At this point, we once again find that defendant's arguments regarding excessive punitive damage awards are unpersuasive. The second basis, the excessive amount of the punitive damages in this case is also uncompelling. The jury's verdict in this regard is well within the limits of reasonability given the findings that it made. For these reasons, defendant's motion for a directed verdict or for a new trial is **DENIED**.

CONCLUSION

After careful consideration and for the forgoing reasons, **IT IS HEREBY ORDERED** that defendant's motion for a new trial pursuant to FRCP Rule 59(b) is **DENIED**; defendant's motion for a new trial or for a directed verdict because the court erred in admitting evidence which was factually inconsistent with the fact determined by the court's partial summary judgment order on the statute of

limitations and legally inconsistent with the premises of that order is **DENIED**; defendant's motion for a new trial based on the inadequacy of the special verdict form used in this case is **DENIED**; defendant's motion for a new trial or for a directed verdict because the court erred in submitting to the jury plaintiff's fraud claim with respect to the 1986 implants is **DENIED**; and defendant's motion for directed verdict on the issue of punitive damages or, in the alternative, for a reduction in the punitive damages award is **DENIED**.

Good cause appearing,

IT IS SO ORDERED.

DATED: ___, 1992

THELTON E. HENDERSON,
CHIEF JUDGE
UNITED STATES
DISTRICT COURT

APPENDIX C

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IN THE UNITED STATES DISTRICT
NORTHERN DISTRICT OF CALIFORNIA

* * *

MARIANN HOPKINS, Plaintiff, vs. DOW CORNING CORPORATION, Defendant.	CASE NO.: C 88 4703 TEH JUDGMENT

This action came on for trial before the Court and a jury, the Honorable Thelton E. Henderson, Chief Judge, Presiding, and the issues having been duly tried and the jury having rendered its verdict,

IT IS ORDERED AND ADJUDGED that the plaintiff MARIANN HOPKINS recover from the defendant DOW CORNING CORPORATION as and for compensatory damages the sum of Eight Hundred Forty Thousand Dollars ($840,000.00) and as and for punitive damages the sum of Six Million Five Hundred Thousand Dollars

($6,500,000.00), with interest on the above sums at the rate provided by law, and her costs of action.

Dated: January 09, 1992

Thelton E. Henderson,
Chief Judge
United States District Court

APPENDIX D

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MARIANN HOPKINS, Plaintiff-Appellee, v. DOW CORNING CORPORATION, Defendant-Appellant.	NO. 92-16132 D.C. No. CV-88-04703-TEH ORDER

Appeal from the United States District Court
for the Northern District of California

Before: LAY,* HUG, and SCHROEDER, Circuit Judges.

The panel, as constituted in the above case, has voted to deny appellant's petition for rehearing. Judge Hug and Judge Schroeder have voted to reject the suggestion for rehearing en banc, and Judge Lay has no recommendation for the suggestion for rehearing en banc.

The full court has been advised of the en banc suggestion and no active judge of the court has requested a vote on whether to rehear the matter en banc.

Fed. R. App. P. 35(b).

The petition for rehearing is **DENIED** and the suggestion for rehearing en banc is **REJECTED**.

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*Honorable Donald P. Lay, Senior United States Circuit Judge for the Eighth Circuit, sitting by designation.

(2)

Supreme Court, U.S.
FILED
NOV 22 1994
OFFICE OF THE CLERK

No. 94-861

IN THE

Supreme Court of the United States

October Term, 1994

DOW CORNING CORPORATION,

Petitioner,

v.

MARIANN HOPKINS,

Respondent.

OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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61pp

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

STATEMENT OF THE CASE 1

A. The Evidence Concerning Punitive Damages 2

B. The Expert Testimony Concerning Causation 11

REASONS FOR DENYING THE WRIT 15

I. THE FIRST QUESTION IS NOT PROPERLY PRESENTED AND HAS NO MERIT 15

II. THE SECOND QUESTION IS NOT PROPERLY PRESENTED AND HAS NO MERIT 21

CONCLUSION 26

TABLE OF AUTHORITIES

Cases:

Baltimore & Carolina Line v. Redman, 295 U.S. 654 (1935) . . . 2

Black v. J. I. Case Co., 22 F.3d 568 (5th Cir. 1994) 17

Boyle v. Lorimar Productions, Inc., 13 F.3d 1357 (9th Cir. 1994) 25

Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc., 492 U.S. 257 (1989) 21

Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) 15-20

Glaros v. H.H. Robertson Co., 797 F.2d 1564 (Fed. Cir. 1986), *cert. dismissed*, 479 U.S. 1072 (1987) 17

Guerrero v. American-Hawaiian Steamship, Co., 222 F.2d 238 (9th Cir. 1955) 2

Heckler v. Campbell, 461 U.S. 458 (1983) 17

Honda Motor Co. v. Oberg, 114 S. Ct. 2331 (1994) . . . 23, 24, 26

International Union of Bricklayers & Allied Craftsman Local Union No. 20 v. Martin Jaska, Inc., 752 F.2d 1401 (9th Cir. 1985) . 17

Jackson v. Virginia, 443 U.S. 307 (1979) 24

Jarrett v. Epperly, 896 F.2d 1013 (6th Cir. 1990) 17

Johnson v. Hugo's Skateway, 949 F.2d 1338 (4th Cir. 1991) 25, 26

Johnson Int'l Co. v. Jackson Nat'l Life Ins. Co., 19 F.3d 431 (8th Cir. 1994) 17

Kentucky v. Stincer, 482 U.S. 730 (1987) 17

Lama v. Borras, 16 F.3d 473 (1st Cir. 1994) 17

Las Palmas Assoc. v. Las Palmas Ctr., 1 Cal. Rptr. 2d 301 (Ct. App. 1991) 23

Latham Seed Co. v. Nickerson American Plant Breeders, Inc., 978 F.2d 1493 (8th Cir. 1992), *cert. denied*, 113 S. Ct. 3037 (1993) 25

TABLE OF AUTHORITIES (continued)

***Cases*:**

Locricchio v. Legal Services Corp., 833 F.2d 1352 (9th Cir. 1987) 17

Lum v. City of Honolulu, 963 F.2d 1167 (9th Cir.), *cert. denied*, 113 S. Ct. 659 (1992) 17

Mallick v. International Broth. of Elec. Workers, 644 F.2d 228 (3d Cir. 1981) 2

Mattison v. Dallas Carrier Corp., 947 F.2d 95 (4th Cir. 1991) . 25

McGoldrick v. Compagnie Generale Transatlantique, 309 U.S. 430 (1940) 17

Mutual Ben. Health & Accident Ass'n v. Thomas, 123 F.2d 353 (8th Cir. 1941). 2

Neal v. Farmers Ins. Exchange, 582 P.2d 980 (Cal. 1978) 23

Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. 1 (1991) . 21, 25

Parsons v. Bedford, 3 Pet. 433, 38 U.S. 433 (1830) 2

Singleton v. Wulff, 428 U.S. 106 (1976) 1

Slocum v. New York Life Ins. Co., 228 U.S. 364 (1913) 2

Sulmeyer v. Coca Cola Co., 515 F.2d 835 (5th Cir. 1975), *cert. denied*, 424 U.S. 934 (1976) 2

Switzerland Cheese Ass'n v. E. Horne's Market, Inc., 385 U.S. 23 (1966) 16

TXO Production Corp. v. Alliance Resources Corp., 113 S. Ct. 2711 (1993) 22, 26

Watson v. Amedco Steel, Inc., 29 F.3d 274 (7th Cir. 1994) . . . 17

Whalen v. Unit Rig, Inc., 974 F.2d 1248 (10th Cir. 1992), *cert. denied*, 113 S. Ct. 1417 (1993) 17

***Federal Rules*:**

Fed. R. App. P. 28(a)(4) 17

Fed. R. Civ. P. 59 . . . . . 21, 23

STATEMENT OF THE CASE

On December 1, 1988, respondent Mariann Hopkins filed suit in the United States District Court for the Northern District of California against petitioner Dow Corning Corporation to recover for injuries she suffered as a result of two sets of Dow Corning breast implants, which she received in breast reconstruction surgery in 1977 and 1986. The 1977 implants burst inside Hopkins' body, flooding her tissues with silicone gel. She sought recovery for bodily injury, including mixed connective tissue disease ("MCTD"), a debilitating autoimmune disease caused by rupture of her silicone-filled implants, and for pain and suffering, medical expenses, and loss of earnings; she also sought punitive damages. *See* Pet. App. at 6-8, 27-30. The primary focus of the case, and the basis for punitive damages, was Hopkins' claim that Dow Corning had fraudulently misrepresented to her, and to the public at large, that its product was safe and tested for use in humans, knowing this to be false. The jury found Dow Corning liable for Hopkins' injuries and awarded her $840,000 in compensatory damages ($473,000 in out-of-pocket losses and $367,000 in pain and suffering damages), plus $6.5 million in punitive damages. *Id.* at 6, 27.

On post-trial motions Dow Corning challenged the verdict on a number of grounds, only one of which it has pursued throughout the appellate process to this Court: its claim that it should receive a new trial because the district court erred in admitting causation testimony from three experts called by Hopkins.[1]

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[1] Dow Corning never moved for a directed verdict on the sufficiency of Hopkins' causation evidence. As demonstrated in Hopkins' brief below, and as Dow Corning has never contested:

> Such an objection appears nowhere in Dow's written Motion for Partial Directed Verdict, filed Nov. 15, 1991 (ER 265); *see also* 9 RT 1109 (limiting directed verdict objections to those appearing in written motion). Moreover, no such objection appeared in Dow's Motion for Judgment as a Matter of Law, filed January 23, 1992 (ER 314). Both the Seventh Amendment and the rule of *Singleton v. Wulff*, 428 U.S. 106, 120-21 (1976), thus flatly bar review on appeal of Dow's sufficiency-of-evidence objection.

Brief of Plaintiff-Appellee, 9th Cir. No. 92-16132, filed Feb. 1, 1993, at 56 n.54. It is well established that the Seventh Amendment bars re-examination

The questions that Dow Corning now attempts to raise are not presented by this case, were not properly presented or passed on in the courts below and, in any event, have no merit. Those points are fully set out below. See pp. 15-26, *infra*. But Dow Corning also raises a broader theme, one not linked in any logical way to the questions presented: a plea that this Court should accept review as a means of correcting some sort of crisis in "mass tort" cases in the lower courts, one that Dow Corning argues is of "national importance." Pet. at 12-18. This argument — which in any event should be presented to Congress or to state legislatures — cannot save Dow Corning's defective petition, for the need for the supposed "remedies" it advocates as a legislative solution is simply not one that applies to this case, as a brief review of the evidence not addressed by Dow Corning makes clear.

A. *The Evidence Concerning Punitive Damages*

In Dow Corning's view, "[m]ass product liability litigation" follows "a well-documented pattern" in which a large jury verdict including punitive damages spawns further widespread litigation, despite the litigation's evident lack of real merit, Pet. at 13-14 & n.9, creating an unwarranted "overburden on judicial systems." *Id.* at 16 n.13. Dow Corning suggests that the fear of huge and unjustified punitive damages verdicts against out-of-state corporations, based on bias and deep pockets, is especially justified in these kinds of cases. *Id.* at 17.

As part of an effort to suggest that the punitive damages verdict in *this* case is part of an alleged national problem, Dow

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of a jury's verdict on a sufficiency objection not preserved at the directed verdict stage. *See, e.g.*, *Baltimore & Carolina Line v. Redman*, 295 U.S. 654, 657-58 (1935); *Slocum v. New York Life Ins. Co.*, 228 U.S. 364, 376-80 (1913); *Parsons v. Bedford*, 28 U.S. (3 Pet.) 433, 446-48 (1830) (Story, J.); *Mallick v. International Broth. of Elec. Workers*, 644 F.2d 228, 233 (3d Cir. 1981); *Sulmeyer v. Coca Cola Co.*, 515 F.2d 835, 846 n.17 (5th Cir. 1975), *cert. denied*, 424 U.S. 934 (1976); *Guerrero v. American-Hawaiian Steamship, Co.*, 222 F.2d 238, 243-44 (9th Cir. 1955); *Mutual Ben. Health & Accident Ass'n v. Thomas*, 123 F.2d 353, 355 (8th Cir. 1941).

Corning claims that the Ninth Circuit's opinion "stated a number of assumed facts that were supported only by the arguments of respondent's counsel," for example, the view that thousands of women were "'at risk of encountering the same fate from which Hopkins suffered,'" and that there was "'evidence that [petitioner] gained financially from its conduct.'" Pet. at 12 n.8 (quoting Pet. App. at 30). To the contrary, at trial Hopkins produced ample evidence, mainly from Dow Corning's own files and employees, to support each and every statement made by the court of appeals implicating Dow Corning in a fraudulent course of conduct. The record demonstrates that for more than a decade Dow Corning, in the pursuit of profit, distributed a product to be placed in women's bodies while knowing that its safety had not been meaningfully tested, knowing that negative safety results were being withheld from the public, knowing that employees were affirmatively lying to customers about safety, and knowing that the public was relying on these misrepresentations, thus endangering many thousands of women. *See* Pet. App. at 8-10, 30. For example:

(1) Dow Corning recklessly "rushed development of silicone gel implants." Pet. App. 8.

Before 1972, Dow Corning was the sole manufacturer of gel-filled breast implants and enjoyed 100 percent of a market worth millions of dollars annually. 6 Reporter's Transcript ("RT") 616:10-11, 615:15. In 1972, however, competitors introduced new implants with a softer, more "natural" feel. Surgeons (the market for implants, 1 RT 73:16-21) quickly decided that Dow Corning's product was "out of style, out of touch." 1 RT 73:5-7. Consequently, competitors "gained a large market share quickly," 6 RT 578:3-4, and Dow Corning suffered "erosion in the market share." 6 RT 578:14-15. "In 1974, the competitive position became very severe," leading Dow Corning to create a special Task Force to "make a product that would be more competitive." 6 RT 575:9-10, 576:3-4.

The crash effort was designed to rush to market an entirely new product in less than five months. Thomas Talcott, a veteran Dow Corning engineer who was rated in the best one percent of Dow Corning employees, 4 RT 573, testified that the weekly

meetings were "charged with bottom line profit" — the "urgency of getting these products on the market to maintain and recover market share." 6 RT 615:10-12. *See also* Plaintiff's Exhibit ("PX-") 55 (collecting Task Force memos and minutes demonstrating members' sense of urgency and constant corner-cutting on safety in the race to market). Talcott testified that his repeated warnings about the product's dangers were ignored by Dow Corning officials, and that Dow Corning's response was to penalize Talcott for raising trouble.[2]

(2) Dow Corning "implants experienced a high rate of rupture" and "leakage." Pet. App. 8-9.

The danger that implants would rupture, pouring silicone gel directly into a woman's body tissue, was clearly known to

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[2] For example, the Task Force rushed into initial experimental implantation in women without giving careful deliberation to quality standards (PX-55 at 2957-58, 2960); it adopted a "single dip" method for making envelopes that guaranteed "bubbles and flaws" because it was "easier" and "cheaper" than the "multiple dip" method that would prevent defective envelopes (6 RT 612:1-18, Pet. App. at 9); it regarded as "allowable flaws," under product specifications, "gross thin spots and . . . significant bubbles" that contributed to implants bursting even as they were being inserted (PX-112); and it ignored concerns that the gel inside the envelope was "extremely fluid in nature" so that "when the devices broke" it would "end up being nonretrievable in people." 6 RT 610:12-16, 611:1-2. Dow Corning ignored these dangers despite the "high rate of rupture" experienced during the initial experimental implants in women. 6 RT 614:6-7. No one on the Task Force, or in higher management, heeded the concerns about these and other dangers that were expressed by Talcott. 6 RT 624:1-7. Talcott "complained . . . vigorously about the introduction of this product" directly to Dow Corning's Director of Research, but to no avail. 6 RT 611:9-20. Instead, at the conclusion of his ten-month effort to prevent Dow Corning from introducing a dangerous product, Talcott was demoted in performance rating from one of Dow Corning's best-rated employees to one of its worst. 6 RT 573. Soon after, he resigned. 6 RT 618:4-5.

In 1975, when Dow Corning launched its product, the Food and Drug Administration ("FDA") lacked power to regulate implanted medical devices, and during all times relevant to this lawsuit Dow Corning's distribution of breast implants was unconstrained by FDA action. Fifteen years after promulgation of the Medical Device Amendments of 1976, 21 U.S.C. § 360c, the FDA ordered that "commercial distribution of [breast implants] must cease" unless each manufacturer could prove the safety of its product. *See* 56 FR 14,620 (April 10, 1991) (final rule). In response, Dow Corning ceased distribution.

Dow Corning at the time it was rushing its product to market, and at all times thereafter. Dow Corning did nothing either to solve these problems or to alert the public to them; instead, it did its utmost to hide them. For example, "several devices . . . ruptured as a surgeon was trying to put them in" during initial experiments with women in early 1975. 6 RT 614:6-7. Nearly a year later, two implants "broke during augmentation surgery for the TV taped demonstrations." Pet. App. at 9 (quoting PX-112). There was the further problem of implant aging: Dow Corning knew that after just two years on the shelf the ability of its implants to resist tearing decreased more than 75 percent. 4 RT 302-03. Moreover, Dow Corning's top management knew that vulnerability to rupture increased once an implant was in a woman's body and was subjected to "elastomer-swell," and that there had even been "cases where the envelope had been 'dissolved by' or 'absorbed by' the gel." PX-87; *see also* 4 RT 299-301. Indeed, given these kinds of problems, Dow Corning's implants could be expected to last only *five years* before they would fail inside a woman. 4 RT 297:1-7.[3]

Dow Corning was also well aware of an entirely different means by which silicone could escape from the envelope, known

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[3] The poor design of the envelope was palpably demonstrated shortly after marketing began, as reports arrived at Dow Corning in increasing numbers about ruptures of the new implants, which directly exposed women to the large amounts of liquid silicone contained in the implants. For example, in 1977 the head of the Task Force noted a number of recent cases involving "broken envelopes and gel found in the pocket," along with claims that the gel had "caus[ed] a reaction, infection, etc." PX-95, at 1376. Dow never published these reports, or the failure rate of its implants: "the data existed within corporate files, but they were never made public." 5 RT 408:7-10. Instead, with full knowledge of this rupture problem, for a full decade Dow Corning marketed its new implants with a "Facts You Should Know" pamphlet specifically written for women and listing "the questions most women ask about breast implants and the answers." PX-3, at 480. The pamphlet stated: "**Q. How long will the implants last? A.** Based on laboratory findings and human experiences to date, a gel-filled implant should last for a lifetime." *Id.* Hopkins was one of the many women who relied on, and was deceived by, this assurance of safety. 6 RT 669, 670:8-9. *See also* 2 RT 135:15-18. The package insert, addressed to surgeons, warned only of the risk of "excessive breast firmness and/or discomfort," not any risk of rupture. PX-1, at 3.

as "gel bleed": the tendency of the silicone gel to leak right through the envelope that was supposed to contain it. Just before its latest model breast implant was released in 1975, some surgeons "noted that after the[y] had been handled for awhile, the surface became oily"; indeed, "some [implants] were bleeding on the velvet in the showcase." PX-55, at 3032. Because Dow Corning was eager to get the product out "on time," the leader of the Task Force made no attempt to solve the problem and simply instructed salesmen to hide it from surgeons when pitching the product. They were instructed in writing to "be sure samples are clean and dry before customer detailing" and "*wash [the implants] with soap & water* in nearest washroom, *dry with hand towels*." PX-55, at 3043 (emphasis added); *see also* Pet. App. at 9. Dow Corning affirmatively worked to cover up this problem in several other ways.[4]

(3) Dow Corning "had knowledge of the harmful effects of silicone on the human body" which it affirmatively concealed from the public. Pet. App. 9-10.

Dow Corning's awareness of the rupture and gel bleed problems was significant in light of its knowledge about the

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[4] In 1976, the same Task Force leader who instructed salesmen to "wash and dry" the implants to remove the gel bleed asserted to a surgeon researcher that the gel bleed phenomenon was "physically impossible." The researcher had discovered the problem on his own, and Dow Corning worked hard to convince him to hold off on publishing his findings. PX-99 at 1-2. The Task Force leader wrote a memo to other employees expressing worry that, if the report was published, the medical and legal communities "may interpret this as proof that our gel causes problems." PX-97 at 1. Soon thereafter, Dow Corning learned that *another* surgeon was proposing to do his own study on the extent of gel bleed and the effects of gel bleed fluid in animals. PX-98 at 1. The Task Force leader worried that this research could be "embarrassing" and possibly "detrimental," *id.*, and Dow Corning ultimately chose to bring the surgeon to corporate headquarters to "convey the impression that we are indeed working in this area" and to indicate "candid reservations" about his proposed independent research. PX-69. At the same time, the Dow Corning scientist in charge of the gel bleed problem decided that the company's data would not "even be considered for release" except after further delay and after approval by top management, given the "obvious sensitivity" of the data and the "severe repercussions in the public sector" that could result from candid disclosure of the gel bleed problem. *Id.*

dangers of liquid silicone. According to one of Dow Corning's top scientists, its new gel implants were about 90 percent liquid silicone by weight, so that the gel was "nothing more than *a delivery system for liquid silicone*." 15 RT 2093:14-19, 2095:15-16 (emphasis added). Dow Corning was well aware of the dangers of liquid silicone to humans. For more than a decade, published medical studies and Dow Corning's own testing had revealed silicone's harmful tendency to migrate from an initial site throughout the human body, and to seriously disrupt the immune system. These studies and tests were corroborated by numerous animal studies, which revealed an immune system response triggered by the same type of silicone contained in Dow Corning's implants. At least six published articles demonstrated these pathological effects. 2 RT 243-44. At the same time, there were clinical reports of cases of "humans who had been injected with silicone fluid . . . showing full-blown reactions attributed to silicone in people that were leading to involvement of the immune system." 2 RT 244.[5]

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[5] The first carefully executed study on liquid silicone confirmed in 1968 that immune reactions can result from silicone in the human body and that silicone migrates to organs that are part of the immune system. 2 RT 261-62. Dow Corning's own animal studies had demonstrated during 1965-68 that silicone tended to concentrate in the lymphatic system and produced a cellular reaction, "which is a hallmark or indicator of a possible immune response." 2 RT 250. *See also* 15 RT 2052:20-22 (concession of Dow Corning's own expert that "distribution of silicone to major organs in the body" was found in study PX-47). One study (DX-60) showed distribution through major organs, including the lymphatic system, and found that *three* of eleven test dogs developed chronic thyroiditis, an autoimmune disease. 15 RT 2049-51. Yet another animal test with 35 dogs, PX-146; 15 RT 2064-65, yielded *four* dogs which "had developed chronic thyroiditis"; indeed, "at the end of the three-year period most of the dogs were [on a] downward trend." 15 RT 2069.

Thus, by the end of the 1960s — more than seven years before Hopkins received her first set of implants — Dow Corning itself perceived significant risks that silicone placed in a human being would migrate throughout the body, collect in organs composing the immune system, and result in adverse cellular reactions indicative of chronic immune reaction. 2 RT 262. Dow Corning's research on the effects of silicone continued into the 1970s up to marketing of its new, lower profile, more liquid implant in 1975. *See, e.g.*, 15 RT 2060 (Dow Corning's own expert admitted that Dow Corning was aware by 1972 that silicone gel would migrate in animals and that there was evidence that silicone would travel to tissues included in the lymphatic and immune systems);

(4) Dow Corning "knew long-term studies of the implants' safety were needed, . . . concealed this information as well as the negative results of the few short-term laboratory tests performed, and . . . continued for several years to market its implants as safe despite this knowledge." Pet. App. 30.

Throughout the time it marketed breast implants, Dow Corning knew that it had *no* meaningful scientific data demonstrating that the implants were safe for use in women. Yet it hid this fact and, worse, without scientific support represented its product as proven to be safe for women.

For example, in just the first year of marketing a key Dow scientist complained in three separate memos, over a span of several months, that Dow Corning was "engulfed in unqualified speculation" concerning safety so that "[n]othing to date is truly quantitative or qualitative," PX-63, ¶ 2; that he had "suggested verbally and in writing that we better get going on a basic long range project relative to gel, its formulation, toxicology, etc.," PX-62; and that he had "proposed again and again that we must begin an indepth study of our gel, envelope, and bleed phenomenon. . . . Time is going to run out for us if we don't get underway." PX-64. These concerns were ignored. Indeed, Dow Corning flouted the standard safety practice of conducting a "lifetime" animal study of a substance (7 years for a dog, 2 years for rats or mice, 2-3 years for a rabbit) before permanently implanting it in humans. 3 RT 41:15-21. Using women as, in effect, human guinea pigs, for the first twelve years that it marketed its new breast implants to many thousands of women, Dow Corning did not test them in any animal for longer than *80 days*. 15 RT 2093.

In its quest for market share and profits, Dow Corning zealously misrepresented its product as safe and worked to thwart independent inquiries into its safety. As a Dow Corning

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3 RT 30:8-20, PX-50 (1972 Dow Corning memorandum indicated that liquid silicone injected into rats produced widespread deposit of silicone throughout the immune systems of rats); 3 RT 34-35 (1974 internal Dow Corning study demonstrated that "silicone has the capacity for stimulating the immune system, specifically the antibody producing arm of the immune system").

salesman candidly testified at trial, if he "told the physician that the long-term physiological effects of silicone are unknown, it would be pretty hard to sell" the implants. 1 RT 68:13-16. Surgeons relied for safety information on contact with Dow Corning's sales force, package inserts, periodic letters, and information pamphlets for patients. 2 RT 133-34, 137-38. Dow Corning perpetuated its scheme through these and other means.

Perhaps most egregious was Dow Corning's handling of the results of a two-year study on four dogs that had received older versions of its breast implants, a study that was completed in 1970. 2 RT 265-70; PX-26. In findings that were "absolutely typical of findings made throughout Dow Corning's testing of plastic gel implants," 3 RT 25:12-13, the raw results of the study indicated that at the end of two years "each of the animals had chronic inflammations at all of the sites of the implants," demonstrating "the existence of . . . an immune reaction." 2 RT 269, 275:2-3. Dow Corning sat on these results for three years. Then, when it published the study in 1973 (PX-166), it rewrote the results to its liking. It falsely indicated "that there was no inflammation at the sites of the implants" at the end of 24 months, 2 RT 275:4-6; PX-166 at 101, and that "[a]fter 2 years the normal health of the dogs was confirmed by close examination." PX-166 at 101.[6]

By 1977, uncertainty concerning the adequacy of Dow Corning's testing and the safety of its implants was "costing Dow business," according to one Dow Corning employee who

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[6] The published version of this study was a blatant attempt to convince plastic surgeons and other medical professionals that Dow Corning's breast implants were safe when Dow Corning clearly knew otherwise. The article stated that Dow Corning's implant has "a 10-year history as a safe and efficacious surgical implant," and further asserted that "plastic surgeons have accepted it generally as a safe and effective device." PX-166, at 100, 103. Expert testimony at trial established that the published study went "a long way towards reassuring [readers] about th[e] long-term safety of the implant." 3 RT 24:13-15. If Dow Corning had disclosed the truth at that time, those same readers would have had "grave reservations about proceeding" with implantation in human beings. 3 RT 25:3-4. By covering up these negative results, Dow Corning ensured that the medical community never received early warning signals, known to Dow Corning, that its product was unsafe.

attended an international plastic surgeons' conference. PX-70 at 1. That employee was well aware that a year earlier another Dow scientist had recommended further safety studies, but "[a]s best I can tell *we have not taken significant action* on any of his recommendations." *Id.* (emphasis added). Yet this same employee told an outright lie to the surgeons and then reported the lie to top Dow Corning employees:

> Both presentations [of the other companies on safety issues] were impressive and well received by the 50 Plastic Surgeons present. Several of our customers, looking to us as leaders in the industry, asked me what we were doing. I assured them, *with crossed fingers*, that Dow Corning too had an active "contracture/gel migration" study underway. *This apparently satisfied them* for the moment, but one of these days they will be asking us for the results of our studies.

Id. at 1-2 (emphasis added). Dow Corning presented no evidence at trial that the memo writer was ever punished, or that the lie was ever corrected.

By 1983, Dow Corning had put some order in its pattern of deception, working out "a position statement in response to customer inquiries regarding the safety of the gels." PX-72, at 856. Dow Corning knew that, in fact, "we have no valid long-term implant data to substantiate the safety of gels for long-term implant use," and the best it could do was to use "inferential data" to construct an "argument" that the gel was "basically loosely cross-linked PDMS polymers," which might be regarded as safe. *Id.* at 858.[7] But, of course, Dow Corning never told

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[7] The same memo suggested that another "r[]ationale" for safety was that the gel was "confined in an envelope of silicone elastomer which does have long-term implant history," but the memo also noted that this theory "supposes that ruptures do not occur or are removed quickly," and that experience had demonstrated "this latter assumption to not be accurate." PX-72 at 856. The scientific "argument" in this position paper was put together by the supervisor of Dow Corning's department responsible for conducting biologic testing on breast implants, 15 RT 2136; PX-72 at 858-60, and was endorsed and made Dow policy by Dow Corning's business quality manager. 15 RT 2137:3-5.

its customers that it had only an "argument" that its implants might be safe. As Dow Corning's business quality manager summarized in 1983, in a memo to eight other Dow Corning employees: "[O]ur product literature (attached) on these gels imply that safety testing to qualify them as implant materials *does* exist and can be obtained readily from Dow Corning." *Id.* at 856 (emphasis added). "To our embarrassment," he noted, this simply was not true. *Id.* In a recommendation that would be ignored for another four years, this manager urged "the necessary work to validate that these gels are safe, calling it a "top priority" given "the extensive population of already implanted devices." *Id.* at 857.

A key Dow Corning study conducted in 1985 noted:

> Both the medical community and the United States Food and Drug Administration continue to question the safety of silicones used for [breast implants]. One major concern that has been identified is the fate of the gel when a mammary prothesis is ruptured *in situ*.

This study revealed that silicone gel placed in the rats rapidly broke "into many smaller masses" and migrated throughout the body. PX-36 at 1. After just *168 days* "only 52% of the gel could be recovered." *Id.* Despite the concern of the FDA and the medical community explicitly noted in this study, Dow Corning concealed the study, marking it "proprietary" and barring distribution outside the company without the approval of the [division vice president]." *Id.* (cover sheet). Thus, a full decade after rushing its experimental product to market, Dow Corning continued to conceal from physicians and patients alike the known dangers of its product. On this record, the Ninth Circuit found, "Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award," and "the jury's award of $6.5 million is reasonable." Pet. App. at 30.

B. The Expert Testimony Concerning Causation

As part of its broad overview about the supposed "national importance" of the subject matter of this case, Dow Corning

warns against the danger that district judges will not "meticulously perform their gatekeeping role to prevent 'junk science' from being introduced into evidence." Pet. at 15. On its face, Dow Corning's analysis is plainly far-fetched. For example, Dow Corning lists as supposed examples of this pattern of frivolous burdening of court dockets the litigation over the Dalkon Shield, DES and asbestos, *id.* at 13 n.9 — suggesting that Dow Corning is against *any* mass-tort litigation, no matter how egregious the corporate misconduct and how many people are widely acknowledged to have been injured as a result. In any event, to support the suggestion that *this case* is part of the supposed national problem Dow Corning makes a series of undocumented and highly selective assertions about the expert testimony on causation in this case, assertions that are demonstrably untrue. Although Dow Corning has not presented any threshhold legal issues concerning expert testimony worthy of review, *see* pp. 15-20, *infra*, even if it had done so, its reliance on misrepresentations about the record independently demonstrates the fact-specific and uncertworthy nature of this case.

Prior to receiving her Dow Corning implants in 1977 as a reconstructive measure to ward off potential cancer, Hopkins was in general a vigorous, athletic woman, one who ran three miles a day. 6 RT 680. Within a year after implantation, however, Hopkins began having difficulty running. She lost her stamina; her knees and feet hurt; her fingers intermittently turned white and blue; her neck and joints hurt; her hands were inflamed; and she suffered numerous upper respiratory problems such as bronchitis. 6 RT 683-84; 8 RT 965; 20 RT 34-35. A year later she was diagnosed with mixed connective tissue disease ("MCTD"), a severe autoimmune disorder causing her body's immune system to attack her body's own tissue. 8 RT 964; 9 RT 1054, 1066-70.[8] The pain and fatigue forced her at first to

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[8] Testimony from Hopkins' treating physicians and from medical experts, corroborated by Hopkins, demonstrated that she did not suffer from MCTD before receiving the Dow Corning implants. *See* 8 RT 889:11-15; 9 RT 1104:2-7. *See also* 9 RT 1071-74, 1092-1103, 1256-57. Moreover, expert

cut back her work hours, 8 RT 965-66, 967:11-12, a year later to take medical leave from work, 8 RT 968, 976, and eventually to undergo numerous hospitalizations, frequent physical therapy, and chronic pain. 8 RT 980-84; 9 RT 1075-78; 20 RT 24, 26, 29-31, 37-38, 44-45, 46-51, 102-06. There is no known cure.

At trial, three experts were called by Hopkins to address the cause of her MCTD.

(1) Dr. Nir Kossovsky. Nir Kossovsky, M.D., is a board-certified anatomic pathologist and a faculty member at the UCLA School of Medicine. He is a nationally recognized authority on the effects of silicone breast implants on the human immune system. He is the author of 84 published scientific articles, half of which deal specifically with "the biological reaction to silicones . . . [including] the biological process by which inflammatory reactions are stimulated by silicone." 7 RT 808:25-809:1. He has personally examined over 200 breast implants and the surrounding tissue following removal from human patients. 7 RT 807, 811:25-812:1. He received an award from the Plastic Surgery Research Council for his pioneering work on the immunological activity of silicone in an animal model. 7 RT 812. The FDA panel that reviews the safety data of breast-implant manufacturers hired Dr. Kossovsky as a consultant. 7 RT 806-07. He has also testified on the subject before Congress. 7 RT 810.

Dr. Kossovsky testified at trial that the proper methodology for determining whether or not a patient's MCTD is caused by silicone in breast implants is "a standard established back in 1976," requiring close scrutiny of "the patient's symptoms," the "exposure to the substance," the "evidence of exposure in the tissues," "corroborative evidence from the animal research literature," and finally "corroborative literature . . . from the basic science fields of chemistry, toxicology, [and] surface science." 7 RT 822:8-25. In applying that methodology to *this*

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testimony established that even if Hopkins' MCTD had first arisen prior to her receiving the implants, "introducing silicone into her body" would have been "like pouring gasoline on a fire," further "inciting the immune system." 3 RT 111:21-22.

case, Dr. Kossovsky testified that he reviewed a wide range of material, including the deposition testimony of Hopkins' doctors, Hopkins' pathology slides and reports, Hopkins' medical records, the medical and scientific literature relating to silicone and autoimmune disease, and several Dow internal research studies on the immunological effects of silicone. 7 RT 813-814, 820. Dr. Kossovsky explained to the jury how he applied this standard methodology in coming to a decision about the cause of Hopkins' MCTD. 8 RT 904-05. Using this methodology he concluded that there exists a "high probability of a causal connection" between Hopkins' MCTD and her ruptured Dow Corning implants. 7 RT 823:1-4.

(2) Dr. Frank Vasey. Frank Vasey, M.D., is a board-certified rheumatologist and a full-time faculty member at the University of South Florida. 7 RT 691. He is a nationally recognized authority on clinical treatment of silicone-induced immune disorders and has testified before Congress, 7 RT 692, and has published on the subject. 7 RT 765. Dr. Vasey has personally seen over 200 patients with silicone-induced immune disorders. 7 RT 692. Dr. Vasey also testified that the preliminary results of an epidemiological study in which he participated "supported the existence of silicone disease." 7 RT 713:18-19.

Dr. Vasey based his testimony in this case on the classic "differential diagnosis" methodology employed by practicing, diagnosing physicians: on Hopkins' medical records, RT 7 RT 719-20, 724-25, and on his own "clinical experience with this disorder [and] the medical literature describing similar cases." 7 RT 723:3-5. After thorough analysis of all key sources of information he concluded that it was "more likely than not" that "Hopkins' MCTD was caused by her silicone implants." 7 RT 722-24.

(3) Dr. Marc Lappe. Marc Lappe, Ph.D, holds a doctorate in Experimental Pathology and currently teaches toxicology — the science of identifying poisons and their effects — at the University of Illinois Medical School. 2 RT 190:20-24. Dr. Lappe is a nationally recognized toxicologist and an authority on silicone and disease. He has testified before the FDA on

"risks of silicone," and in 1990 was appointed as a toxicological advisor to the FDA to "review data concerning the safety of silicone breast implants." 2 RT 202. Dr. Lappe has served as Chief Toxicologist of the California Department of Industrial Relations, where he was responsible for determining the safety of substances and materials for use by human beings. 2 RT 198. Throughout his career, Dr. Lappe has analyzed human and animal test data and has served on "human subject review committees that make decisions as to the acceptability of proceeding with direct testing or implantation of materials into humans." 3 RT 22.

Using the standard methodology employed in his field, Dr. Lappe reviewed "the medical reports and data on Mariann Hopkins," 2 RT 203:19, tissue tests, animal data, and the literature on silicone products, including every single internal Dow Corning study presented in the case. 2 RT 204:24-205:1, 240; 19 RT 2462:12-15. Based on careful analysis of these materials, Dr. Lappe concluded: "[T]he silicone which inevitably entered Mariann Hopkins' body at or before the observed time of rupture from these implants was the major causative factor in her mixed connective tissue disease." 3 RT 108:24-109:15. He reiterated: "There is no doubt in my mind that silicone was the major contributing factor to what we would call the pathogenesis or the development of this severe debilitating disease and its constellation of secondary effects." 3 RT 112:15-18.

REASONS FOR DENYING THE WRIT

I. THE FIRST QUESTION IS NOT PROPERLY PRESENTED AND HAS NO MERIT

In its first question presented, Dow Corning asks:

> May a federal appellate court after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ___, 125 L. Ed.2d 469, 113 S. Ct. 2786 (1993), uphold admission of expert scientific testimony when the district court refused to make any preliminary assessment of its scientific reliability and the proffered testimony met none of *Daubert*'s reliability criteria?

Pet. at i. But Dow Corning has not demonstrated that this question has something to do with *this case* and could be reached on the record below. Setting aside Dow Corning's undocumented assertions to the contrary, it is clear that Dow Corning made no objection at trial to the reliability of the methodology of Hopkins' experts, and that the district court considered and rejected each and every expert testimony objection that Dow Corning actually raised.

(1) The bulk of Dow Corning's expert testimony argument in its petition has, in fact, nothing to do with *Daubert* or the methodology of Hopkins' three experts who testified at trial. Instead, Dow Corning complains that the court of appeals erred in declining to grant its *summary judgment* motion which argued that Hopkins' evidence was *insufficient* (not inadmissible) to prove causation under California law. Dow Corning asserts:

> The panel undertook no review of the evidence presented by respondent to controvert petitioner's summary judgment motion challenging the sufficiency of her causation evidence to raise a triable issue of fact. If it had compared respondent's deposition testimony on causation with the requirements of *Daubert*, it should have been evident that her causation evidence was insufficient to permit her to go to trial.

Pet. at 18-19. Dow Corning contrasts the decision below with decisions of other circuits upholding summary judgments, Pet. at 19-20, and concludes that "petitioner's summary judgment motion should have been granted." Pet. at 20.

There are four reasons why this plea cannot be taken seriously as a basis for *certiorari*.

First, the Ninth Circuit "undertook no review" of the district court's denial of summary judgment on the sufficiency of the causation evidence for the simple reason that *it was not asked to do so*. In its docketing statement, Dow Corning assigned thirteen different points for appeal but excluded this summary judgment ruling. Dow Corning likewise failed to include the

point in any of its briefs or arguments, thereby waiving it.[9]

Second, review of the district court's denial of Dow Corning's summary judgment motion is now unavailable due to the intervening trial and jury verdict. After all, "the denial of a motion for a summary judgment because of unresolved issues of fact does not settle or even tentatively decide anything about the merits of the claim. It is strictly a pretrial order that decides only one thing — that the case should go to trial." *Switzerland Cheese Ass'n v. E. Horne's Market, Inc.*, 385 U.S. 23, 25 (1966). For that reason, "the denial of a motion for summary judgment is not reviewable on an appeal from a final judgment entered after a full trial on the merits." *Locricchio v. Legal Services Corp.*, 833 F.2d 1352, 1359 (9th Cir. 1987). This appears to be the uniform rule in the federal courts of appeals; indeed, in his *Locricchio* opinion Judge Sneed noted that "[a]fter considerable research, we have found no case in which a jury verdict was overturned because summary judgment had been improperly denied." *Id.*[10]

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[9] *See* Fed. R. App. P. 28(a)(4); *International Union of Bricklayers & Allied Craftsman Local Union No. 20 v. Martin Jaska, Inc.*, 752 F.2d 1401, 1404 (9th Cir. 1985) ("[W]e will not ordinarily consider matters on appeal that are not specifically and distinctly raised and argued in appellant's opening brief"). Obviously, Dow Corning's sudden desire for review of a summary judgment motion that it has ignored for more than four years hardly qualifies this as the kind of "exceptional case" worthy of review despite Dow Corning's failure to raise the issue in the court of appeals. *See, e.g., Kentucky v. Stincer*, 482 U.S. 730, 747 n.22 (1987); *Heckler v. Campbell*, 461 U.S. 458, 468 n.12 (1983); *McGoldrick v. Compagnie Generale Transatlantique*, 309 U.S. 430, 434-35 (1940).

[10] *See also Watson v. Amedco Steel, Inc.*, 29 F.3d 274, 1994 U.S. App. LEXIS 17036, *6-16 (7th Cir. 1994); *Black v. J. I. Case Co.*, 22 F.3d 568, 571-72 (5th Cir. 1994); *Johnson Int'l Co. v. Jackson Nat'l Life Ins. Co.*, 19 F.3d 431, 434 (8th Cir. 1994); *Lama v. Borras*, 16 F.3d 473, 476 n.5 (1st Cir. 1994); *Whalen v. Unit Rig, Inc.*, 974 F.2d 1248, 1250-51 (10th Cir. 1992), *cert. denied*, 113 S. Ct. 1417 (1993); *Lum v. City of Honolulu*, 963 F.2d 1167, 1170 & n.1 (9th Cir.), *cert. denied*, 113 S. Ct. 659 (1992); *Jarrett v. Epperly*, 896 F.2d 1013, 1016 (6th Cir. 1990); *Glaros v. H.H. Robertson Co.*, 797 F.2d 1564, 1573 (Fed. Cir. 1986), *cert. dismissed*, 479 U.S. 1072 (1987).

Third, if Dow Corning wished to obtain review of the sufficiency-of-the-evidence argument raised in its summary judgment motion on causation, it could have renewed the objection at the directed verdict stage. It elected not to do so, and this Court's settled Seventh Amendment jurisprudence therefore bars any sufficiency-of-the-evidence review on the causation issue. *See* note 1, *supra* (citing cases).

Fourth and finally, even if Dow Corning could revive its summary judgment motion in this Court, nothing in it is relevant to the *Daubert* inquiry that is the subject of the first question presented. In general, of course, *Daubert* concerns the admissibility of evidence in federal court, not its sufficiency under governing substantive law. More specifically, *Daubert* emphasized that in making Rule 702 admissibility decisions, "[t]he focus, of course, must be solely on principles and *methodology*, not on the conclusions they generate." 113 S. Ct. at 2797 (emphasis added). But Dow Corning's summary judgment motion attacked only the *conclusions* of plaintiffs' treating physicians (none of whom ultimately was called by Hopkins on the causation issue at trial). Dow Corning argued that these experts' conclusions were not expressed at the level of "reasonable medical probability" required under California law,[11] an issue that is simply not governed by Rule 702 as explicated in *Daubert*.

(2) In a further bid to convince this Court that the first question is actually presented by this case, Dow Corning claims that it "filed a motion *in limine* to exclude the testimony of respondent's three designated expert causation witnesses, Drs. Marc Lappe, Nir Kossovsky and Frank Vasey, because none of

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[11] *See* Defendant's Memorandum of Points and Authorities in Support of Motion for Summary Judgment, filed Nov. 20, 1989, at 7 ("The testimony of Plaintiff's treating physicians Dr. Donald R. Laub, Dr. Louis E. Pelfini, Dr. Stephen Gospe, and Dr. Hugh O'Neill McDevitt does not establish within a reasonable medical probability that Plaintiff's MCTD is causally linked to exposure to silicone"); *id.* at 10 (arguing that "more probably than not" standard must be met and that "not one [of Hopkins' physicians] is able to state within a reasonable medical probability that Plaintiff's condition is causally related to silicone or her breast implants").

their opinions was scientifically reliable or based on a methodology or technique accepted by any relevant scientific community." Pet. at 2. This claim is completely false. In fact, the *in limine* motion (which the district court denied; it did not refuse to rule on it) was a narrow one. The motion sought only to limit the *scope* of the three experts' testimony to their supposedly narrow areas of qualification and to restrict them from relying on certain pieces of data; Dow Corning made no effort to demonstrate that the *methodology* employed by these experts required the wholesale exclusion of the testimony. Hopkins documented this point in her Ninth Circuit brief without contradiction by Dow Corning.[12]

Because Dow Corning's *in limine* motion focused on the experts' qualifications (not on their methodology), it is understandable that — in rejecting Dow Corning's argument "that the district court erred in not holding a formal hearing" — the court of appeals stated that the district court was required only to

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[12] *See* Brief of Plaintiff-Appellee, 9th Cir. No. 92-16132, filed Feb. 1, 1993, at 46 & n.41:

> Dow's narrow *in limine* motion, the denial of which it now appeals, Dow Br. 47, invoked only *two* grounds for exclusion: (1) "that these experts do not qualify as experts under Federal Rule of Evidence 702" and "may attempt to offer expert opinion testimony which is beyond their specific and designated areas of expertise," and (2) that "under Federal Rule of Evidence 703, the Court should exclude any testimony by plaintiffs' experts where there is no acceptable or reliable basis for their opinion." Motion *in Limine* to Exclude Expert Testimony, filed June 18, 1991, at 2-3. *See also* Motion at 36 (limiting motion to Rules 702 and 703 and "requesting the Court to limit the subject matters" of testimony "to only those areas they were disclosed to testify regarding *and* in which they are qualified to testify") (emphasis in original). Nowhere in its motion did Dow argue that the ultimate expert opinions of Hopkins' experts should be excluded because the scientific methodology they employed was novel and not "generally accepted by the scientific community in the field in which the expert is testifying," Dow Br. 44-45, and Dow thus has waived this claim.

Nowhere in its reply brief, filed March 1, 1993, did Dow Corning suggest that its *in limine* motion attempted to prove flaws in the methodology of Hopkins' experts that would render their testimony entirely inadmissible.

"make a determination as to the proposed expert's qualifications." Pet. App. at 21. There is nothing "irreconcilab[le]" between this passage and *Daubert*; indeed, at the beginning of this same paragraph, the court of appeals made clear that "the trial judge must first determine, pursuant to Rule 104(a) and Rule 702, whether the expert is proposing to testify to scientific knowledge that will assist the trier of fact." Pet. App. at 20-21. Thus, Dow Corning engages in fantasy in suggesting, in its first question presented, that the Ninth Circuit upheld a district court's "refus[al] to make any preliminary assessment of . . . scientific reliability." Pet. at i.

(3) Finally, Dow Corning contends that its objections *during* trial "to the admission of respondents' expert witnesses should have been sustained." Pet. at 21. As Dow Corning belatedly documented in a post-argument letter brief, its "repeated objections to the testimony of plaintiffs' experts were overruled" at trial. Appendix B hereto, at **A6** n.5 (citations omitted). However, none of the 22 pages cited had anything to do with a *Daubert*-style analysis of *the methodology* of Hopkins' experts, as Hopkins documented without contradiction by Dow Corning. *See* Appendix C hereto, at **A14** n.3 (demonstrating that "the citations reveal minor objections," mostly to the form of testimony).

In the end, Dow Corning never preserved any *Daubert* issue below, so that the first question could never be reached by this Court even if the district court did refuse to rule when requested, which it did not. Dow Corning simply failed to object at trial to the *methodology* used by any of Hopkins' experts. Independently, there is no evidence in the trial record to contradict the testimony of Hopkins' experts that the methodology they used is valid and reliable, and indeed standard in their fields. *See* pp. 13-15, *supra*. Dow Corning makes no attempt in its petition to show the contrary; indeed, it does not even discuss the trial record, preferring to concentrate on the "evidence before the district court in ruling on the pre-trial motion." Pet. at 2; *see id.* 3-6 (reviewing deposition testimony only). Thus, the first question is not presented, and none of the objections actually raised by Dow Corning has any merit.

II. THE SECOND QUESTION IS NOT PROPERLY PRESENTED AND HAS NO MERIT

In its second question presented, Dow Corning attempts to raise the issue of the procedures by which a federal court, sitting in diversity, may review a punitive damage award. The gravamen of Dow Corning's argument is that such review is circumscribed by the Re-Examination Clause of the Seventh Amendment. Dow Corning's confused and contrived argument turns out to be quite radical. For example, Dow Corning openly argues that Fed. R. Civ. P. 59 is facially unconstitutional, at least in cases where the plaintiff seeks punitive damages — despite this Court's decision approving Rule 59 review in *Browning-Ferris Indus. of Vermont, Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257, 279-80 (1989).

Yet in the end there is no occasion to reach Dow Corning's proffered question because its argument was not raised below and thus is not properly presented here. Notably, Dow Corning did not include its new-found punitive damages point either in its petition for rehearing or in its motion to stay the mandate in the court of appeals, even though Dow Corning listed in the latter the grounds on which "[t]he Petition for Writ of Certiorari will be substantially based." Indeed, not only did Dow Corning fail to raise its constitutional claims below, but it pursued below precisely the *opposite* argument from what it advocates here.

(1) Dow Corning barely cites the procedural history of this case concerning punitive damages, or even the decision of the Ninth Circuit regarding that issue. In fact, in the court of appeals Dow Corning sought to invalidate the punitive damage award on the ground that it did not comport with the standard announced in *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22 (1991). *See* Pet. App. 28-30, 38; *see also* Appellant's Opening Brief, 9th Cir. No. 92-16132, filed Nov. 27, 1992, at 57 (arguing that "the standards and procedure for awarding punitive damages applied in this case do not meet the constitutional minima required by *Haslip*").

Although the court of appeals cited *Browning-Ferris* and Rule 59, it also performed a *Haslip*-style review that fully

satisfied procedural due process. The court enumerated the factors prescribed in *Haslip* for the judicial review of punitive damages. *See* Pet. App. 28-29. The court also discussed the substantive criteria for the assessment of punitive damages outlined in *TXO Production Corp. v. Alliance Resources Corp.*, 113 S. Ct. 2711, 2721-24 (1993). *See* Pet. App. 29-30. The court of appeals explained that the award here was plainly justifiable under this precedent:

> The evidence presented at trial established that a large number of Dow silicone gel breast implants had been implanted in thousands of women. Each of these women was at risk of encountering the same fate from which Hopkins suffered. Therefore, Dow's conduct in exposing thousands of women to a painful and debilitating disease, and the evidence that Dow gained financially from its conduct, may properly be considered in imposing an award of punitive damages. Moreover, given the facts that Dow was aware of possible defects in its implants, that Dow knew long-term studies of the implants' safety were needed, that Dow concealed this information as well as the negative results of the few short-term laboratory tests performed, and that Dow continued for several years to market its implants as safe despite this knowledge, a substantial punitive damages award is justified. Coupled with the facts that Dow is a wealthy corporation and that Dow made a considerable amount of money from the sale of its implants, the jury's award of $ 6.5 million is reasonable in light of *TXO* and *Haslip*. Therefore, we conclude that Hopkins presented sufficient evidence to uphold the jury's findings with respect to the punitive damages award.

Id. at 30.

Dow Corning now evidently believes that it should never have received the benefits of *Haslip*'s procedures for judicial review in the first place because of the Seventh Amendment. But Dow Corning surely cannot be permitted to reverse course 180 degrees and to assign as error what it previously contended was required by due process. And, even if it could, it is difficult to

see how Dow Corning would have standing to assert that it enjoyed *more* procedures than it was constitutionally entitled to receive.

(2) Dow Corning makes no attempt to show that the question presented would make any difference in the outcome of this case. In fact, a California court may set aside a damages award only where it "appears excessive or . . . is so grossly disproportionate as to raise a presumption that it is the result of passion or prejudice." *Neal v. Farmers Ins. Exchange*, 582 P.2d 980, 990 (Cal. 1978). Like Rule 59 review, California "passion and prejudice" review is measured against the criteria applied by the jury. *See Las Palmas Assoc. v. Las Palmas Ctr.*, 1 Cal. Rptr. 2d 301, 323 (Ct. App. 1991) (review denied). Dow Corning's failure to analyze the concrete implications of the difference between state-court review and Rule 59 review means that its question presented is purely academic.

(3) In any event, Dow Corning's criticisms of judicial review in federal court are misplaced. Dow Corning admits that "[t]his Court has relied heavily on the lengthy history of the common law" in deciding whether punitive damage schemes comport with procedural due process, but maintains that "the common law has nothing to say about federal procedural rules." Pet. at 24. To the contrary: this Court recently indicated that "traditional practice provides a touchstone for constitutional analysis," and that the "the common law method of assessing punitive damages d[oes] not violate procedural due process." *Honda Motor Co. v. Oberg*, 114 S. Ct. 2331, 2335, 2339 (1994).[13] Although the common law may play a greater role in

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[13] Under the common law approach, judges "generally defer[] to the jury's determination of damages," and ask only whether "the damages are outrageous, and all mankind at first blush must think so," or whether damages are "so monstrous and excessive, as to be in themselves an evidence of passion or partiality in the jury." *Oberg*, 114 S. Ct. at 2336 (citations omitted). Although this Court did not definitively resolve precisely "what standard of review is constitutionally required," *id.* at 2341 n.10, this Court explained that:

> Although courts adopting a more deferential approach use different verbal formulations, there may not be much practical difference between

prescribing the *content* of state procedural rules than it does with respect to their federal counterparts, the *constitutionality* of federal and state rules must be judged by the same baseline of traditional practice. Indeed, in the very next section of its petition Dow Corning contends that, "[n]o less process is due under the Fifth Amendment than under the Fourteenth Amendment." Pet. at 25. If the common law approach is constitutional in state court, it is permissible in federal court as well.[14]

(4) Any claim that the standard California jury instruction on punitive damages is somehow inadequate is unavailable here because it was not pressed on appeal or passed on in the Ninth Circuit. Indeed, in a post-argument letter in the court of appeals, Dow Corning conceded that it had no remaining constitutional objections to affirmance of the jury's award in its entirety.[15] Nor is Dow Corning seeking review of the instruction in this Court. In truth, it is exceedingly difficult to determine what Dow Corning *is* seeking.

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review which focuses on "passion and prejudice," "gross excessiveness," or whether the verdict was "against the weight of the evidence." All of these may be rough equivalents of the standard this Court articulated in *Jackson v. Virginia*, 443 U.S. 307, 324 (1979) (whether "no rational trier of fact could have" reached the same verdict).

Id.

[14] If anything, the jury's powers were greater at the time of the adoption of the Fifth Amendment in 1791 than they were at the time of the adoption of the Fourteenth Amendment in 1868. *See Oberg*, 114 S. Ct. at 2348 (Ginsburg, J., dissenting).

[15] In a letter brief dated July 6, 1993, Dow Corning narrowed its argument to the claim that *if* it prevailed on its statute-of-limitations argument and thereby eliminated $367,000 of Hopkins' compensatory damages (her award for pain and suffering), and she recovered only "her out-of-pocket losses [$473,000], the amount of punitive damages awarded are so grossly excessive as to violate the substantive component of the Due Process Clause." Appendix B hereto, at **A9**. However, the Ninth Circuit ended up rejecting Dow Corning's statute-of-limitations argument, Pet. App. at 10-20, and upheld the compensatory award in full, *id.* at 27, thus mooting Dow Corning's sole remaining objection to the amount of the punitive damages award.

In any event, the jury instruction here[16] — which is the California pattern jury instruction for punitive damages — provided more guidance than the instruction approved in *Haslip*, which instructed the jury merely that, in setting the amount of punitive damages, "you must take into consideration the character and degree of the wrong as shown by the evidence and necessity of preventing similar wrong." 499 U.S. at 6 n.1; *see also Boyle v. Lorimar Productions, Inc.*, 13 F.3d 1357 (9th Cir. 1994) (the California instruction goes beyond the requirements of *Haslip*).

(5) Finally, Dow Corning asserts that "[t]he circuits are in conflict on the application of *Haslip* to punitive damage awards in diversity cases." Pet. at 25 (quoting argument heading). Dow Corning relies on but two cases for this rather sweeping statement, and its description of the cases is inaccurate.[17] In

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[16] "If you determine that punitive damages should be assessed against the defendant, in arriving at the amount of such an award, you must consider: (1) The reprehensibility of the conduct of the defendant. (2) The amount of punitive damages which will have a deterrent effect on the defendant in light of the defendant's financial condition. (3) That the punitive damages must bear a reasonable relation to the injury, harm, or damage actually suffered by the plaintiff." ER 302.

[17] The Eighth Circuit case on which Dow Corning relies — *Latham Seed Co. v. Nickerson American Plant Breeders, Inc.*, 978 F.2d 1493 (8th Cir. 1992), *cert. denied*, 113 S. Ct. 3037 (1993) — does not mention the Seventh Amendment, *Erie*, or any of the supposed problems with punitive damages review in diversity cases purportedly identified in Dow Corning's petition.

And Dow Corning fails to give this Court a complete account of developments in the Fourth Circuit after the decision in *Mattison v. Dallas Carrier Corp.*, 947 F.2d 95 (4th Cir. 1991). In *Johnson v. Hugo's Skateway*, 949 F.2d 1338 (4th Cir. 1991), decided after *Mattison*, a panel of the court of appeals explained the limits of *Mattison*:

> We find misfounded concerns about the Seventh Amendment if such [post-trial] review is conducted by the district court. . . . [T]he district court would be conducting a narrow review based on the evidence in the record. We are not in the case of such review asking the district judge to consider factors that were not before the jury. Rather, we are simply suggesting that the district judge review the jury's factual determination to draw a *legal* conclusion (i.e., the reasonableness of the punitive

any event, both cases predate *Oberg* and *TXO*, which provide ample guidance to the lower courts as to the judicial review of punitive damage awards. And the instant case would in any event be an exceedingly poor vehicle to review the question presented, since Dow Corning *never asked* the court of appeals its view as to "the application of *Haslip* to punitive damage awards in diversity cases." Pet. at 25 (quoting argument heading).

CONCLUSION

The questions in Dow Corning's petition are not properly presented on the record of this case and are without merit. The prudential concerns Dow Corning raises about mass tort litigation have no logical connection to these questions and, in any event, do not apply to this case. Dow Corning's petition should be denied.

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damages award). Accordingly, this narrow review does not run afoul of the Seventh Amendment.

949 F.2d at 1351 n.6 (citation omitted and emphasis in original).

The Fourth Circuit reconsidered *Hugo's Skateway en banc*. The court did not expressly adopt the panel's analysis, but it squarely rejected the argument that a State's scheme for post-trial review is irrelevant to a federal court sitting in diversity. In carefully chosen language, the Court explained:

> if state law assigns the trial or appellate court a post-verdict role in assessing the reasonableness of a punitive damages award and specifies certain factors to be considered in making that assessment, . . . this body of substantive law must also be applied in federal court, but in a manner that permits consideration by *the jury* as the sole fact finder, rather than by the judge.

Johnson v. Hugo's Skateway, 974 F.2d 1408, 1417 (4th Cir. 1992) (*en banc*). Thus, there is significant doubt over the continued vitality of *Mattison* even in the Fourth Circuit.

Respectfully submitted,

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APPENDICES

APPENDIX A

Supplemental Authorities of Appellee,
9th Cir. No. 92-16132, dated June 29, 1993 . . . . . A1

APPENDIX B

Letter Brief of Appellant,
9th Cir. No. 92-16132, dated July 6, 1993 . . . . . A3

APPENDIX C

Letter Brief of Appellee,
9th Cir. No. 92-16132, dated July 15, 1993 . . . . . A10

APPENDIX A

LAURENCE H. TRIBE
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June 29, 1993

Ms. Cathy A. Catterson
Clerk, U.S. Court of Appeals
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121 Spear Street, 6th Floor
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RE: Supplemental Authorities, Hopkins v. Dow Corning Corp., No. 92-16132

Dear Ms. Catterson:

On behalf of appellee Mariann Hopkins, I wish to call to the attention of the panel (Judges Hug, Schroeder and Lay) two recent decisions of the U.S. Supreme Court.

First is TXO Production Corp. v. Alliance Resources Corp., No. 92-479, decided June 25, 1993 (slip opinion attached). In its reply brief at 29 n.51, and at oral argument, appellant Dow Corning argued that the decision in TXO might suggest a procedural deficiency with the post-trial review in this case. However, in TXO (unlike this case), the trial court did not even issue a written opinion explaining its ruling upholding the punitive damages award, but the Supreme Court, by a 6-to-3 margin, held that the "trial judge's failure to articulate the basis for his denial of the motions" was not a violation of procedural due process. Slip op. at 20 (Stevens, J., joined by Rehnquist, C.J. and Blackmun, J.); see also concurrence of Kennedy, J. and concurrence of Scalia and Thomas, JJ. Nor is anything else in TXO helpful to Dow.

Second is Daubert v. Merrell Dow Pharmaceuticals, Inc., No. 92-102, decided June 28, 1993 (slip opinion attached), relevant to Dow's argument in its reply brief at 17-20, and at oral argument, that the District Court's evidentiary decisions in this case must be reviewed de novo, and reversed, because "the steps each expert

used in moving from the raw data to his opinions [did not] follow[] a methodology that is generally accepted within the scientific community." Dow predicted at oral argument that the Supreme Court's decision in Daubert would vindicate its attack on the District Court. Nothing of the sort occurred. Daubert unanimously overruled the Frye "general acceptance" test. Slip op. at 4-8; see also partial concurrence of Rehnquist, C.J., and Stevens, J. By a 7-to-2 margin, Daubert also reaffirmed the "liberal thrust" of the Federal Rules of Evidence, slip op. at 8; agreed with Hopkins' brief at 53 that the focus of expert testimony admissibility analysis "must be solely on principles and methodology, not on the conclusions that they generate," slip op. at 14; and held that conclusions of experts may be challenged only through the adversary process, backed up by sufficiency-of-evidence analysis, slip op. at 15-16. Dow's strategy in the trial court of attacking the conclusions of Hopkins' experts rather than challenging any particular principle or methodology relied on by those experts, coupled with Dow's waiver of any sufficiency-of-evidence objection (Hopkins' brief at 55-56), renders Daubert of no help to Dow.

Sincerely,

(signature)
Laurence H. Tribe

cc: Shirley M. Hufstedler, Esq.
Frank C. Woodside, III, Esq.

APPENDIX B

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July 6, 1993

Honorable Proctor Hug
U.S. Circuit Judge
Honorable Mary Schroeder
U.S. Circuit Judge
Honorable Donald Lay
Senior U.S. Circuit Judge
United States Court of Appeals
for the Ninth Circuit
P. O. Box 547
San Francisco, CA 94101

In re: Hopkins v. Dow-Corning Corp., No. 92-16132

Dear Judges, Hug, Schroeder and Lay:

During the oral argument of the above-entitled case, I requested the Court's permission to file a supplementary brief to discuss the impact of Daubert v. Merrell Dow Pharmaceuticals, Inc., ___ U.S. ___ (1993) and TXO Production Corp. v. Alliance Resources Corp., ___ U.S. ___ (1993), neither of which had been handed down when this case was argued. I now renew my request and tender herewith this supplementary letter brief addressed to these two opinions as they apply to this case.

Introduction. In her letter, dated June 29, 1993, entitled "Supplemental Authorities", plaintiff states that Daubert does not

help defendant because at trial defendant only attacked the conclusions of plaintiff's experts rather than challenging the experts' methodology and that defendant waived any sufficiency of the evidence objection. The record contradicts the plaintiff's assertions.

In defendant's pretrial motion to exclude the testimony of plaintiff's causation experts, in its objections to the testimony of those experts at trial, in its motion for a directed verdict, and in its post-trial motions, defendant very specifically challenged the admissibility of the testimony on the grounds, among others, that the methodology used by these experts had no scientific basis and their opinions are not founded on any principles accepted by science. Defendant challenged the sufficiency of the evidence to go to the jury in its directed verdict motion because plaintiff's expert witness testimony on causation was inadmissible, and no other evidence in the record existed to establish causation. In its opening brief, defendant argued:

> "4. The district court prejudicially erred in permitting plaintiff to go to the jury on her personal injury claims because she failed to produce substantial evidence that her disorders and diseases were causally related to her prostheses" (Defendant's Opening Brief at 44).

The Daubert decision. The Supreme Court held that the "general acceptance" test of Frye was not the exclusive test for admitting expert scientific testimony after the Federal Rules of Evidence, but acceptance by an identified segment of the scientific community was relevant in determining admissibility. Slip Op'n at 8, 14. The Court was explicit that the district court must hold a Rule 104(a) hearing to determine admissibility of such testimony; the testimony is not admissible unless the expert is proposing to testify to scientific knowledge that will assist the trier of fact to understand or to determine a fact in issue.[1/]

[1/] "Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly

In reaching its Rule 104(a) determination, the district court must decide whether the proposed testimony is grounded in the methods and procedures of science.[2/]

Daubert validates defendant's contention that admission of plaintiff's scientific expert testimony was prejudicial error. Defendant's pretrial and post-trial motions and its objections at trial leave not the slightest doubt that defense counsel attacked the admissibility of plaintiff's expert witnesses precisely on the grounds that Daubert accepted. In each instance, defendant attacked the causation testimony proffered by Drs. Lappé, Vasey, and Kossovsky because the steps each used in forming his opinions were not based on existing scientific knowledge or on any scientifically accepted methodology, and none was validated.

The facts that the plaintiff suffered from MCTD and that the defendant's prostheses were implanted in her at some time during the course of her disease were never disputed. In reaching their respective conclusions, each of the experts relied on plaintiff's medical history, but that history contained nothing about the cause of her disease. Dr. Lappé reached his conclusion from his rereading of hundreds of defendants' animal studies. He was unable to cite any published literature, any study, or any experiment that agreed with his rereading of the animal studies, none that extrapolated the results of animal studies to human beings, and none that found a causal connection between implantation of medical grade silicone and human autoimmune disease. Moreover, Dr. Lappé, an experimental pathologist, was not qualified in the fields of human

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can be applied to the facts in issue. Slip Op'n at 12. [Emphasis added; footnote omitted.]

[2/] "The subject of an expert's testimony must be 'scientific . . . knowledge.' The adjective 'scientific' implies a grounding in the methods and procedures of science. Similarly, the word 'knowledge' connotes more than subjective belief or unsupported speculation. . . . [I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation - i.e., 'good grounds,' based on what is known. . . . [T]he requirements that an expert's testimony pertained to 'scientific knowledge' establishes a standard of evidentiary reliability." Slip Op'n at 9-10.

disease or in human reactions to implanted medical grade silicone.

Dr. Vasey had published a case study in which he hypothesized a possible connection between silicone-gel implants and autoimmune disease, but his sole methodology in turning his hypothesis into an opinion that the implants more probably than not caused her disease was his observations of his patients.[3/]

Dr. Kossovsky relied on an animal study that he had himself conducted, but he conceded that animal studies cannot be successfully extrapolated to human beings; he ultimately conceded that his opinion was based on an untested hypothesis.[4/]

The district court declined to hold a Rule 104(a) hearing. Throughout the proceedings below, the court was under the mistaken belief that its only obligation before admitting the proffered expert testimony was a preliminary determination of the experts' qualification.[5/] The district court's mistaken understanding of its obligation is most clearly revealed in the colloquy with defense counsel during the argument on defendant's post-trial motions in

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[3/] Such non-replicable, untested, non-peer reviewed observations are not acceptable in any scientific community as more than a basis for a hypothesis.

[4/] Extrapolating animal studies to human beings was held inadmissible in Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir. 1992), cited with approval in Daubert. Slip Op'n at 16. The Turpin court upheld summary judgment in favor of the manufacturer of a drug which plaintiffs contended had caused birth defects. "The decisive weakness in the plaintiffs' animal studies is that the factual and theoretical basis articulated for the scientific opinion stated will not support a finding that [the drug] more probably than not caused the birth defects here." 959 F.2d at 1359. In our case, as in Turpin, the proffered expert testimony was based on personal opinions, not science.

Turpin, as well as Viterbo v. Dow Chem. Co., 826 F.2d 420 (5th Cir. 1987) were cited and discussed in defendants' opening brief at 45, 46, 49, and in its reply brief at 22, 24.

[5/] Defendants' in limine motion to exclude plaintiffs' expert testimony is found, in part, in Excerpts of the Record at 148; the motion was denied by a telephone call from the district court's clerk. Defendant's repeated objections to the testimony of plaintiffs' experts (1 RT 227, 230, 239, 240, 250, 272; 3 RT 24, 52, 57, 75, 77, 95, 107; 7 RT 704, 709, 713, 722, 728, 741, 821, 825, 830) were overruled.

which the court expressed incredulity that it was obliged to go behind the face of offered expert testimony to determine whether there was any acceptable scientific basis for it.[9]

Defense counsel insisted that the court had the obligation to inquire into the basis of the testimony using a Rule 104 hearing at which the court should ask:

> "Is there any basis for that [opinion]? . . . [I]s there any literature? Are there any studies? Have you ever been taught thus and so? . . . [I]f the answer is . . . no . . . then I would submit that the opinion would be inadmissible, and that's what we have here. [T]here has to be some basis in science and that is what the Sixth Circuit is taking about . . . so that you don't just have junk science coming into court rooms. .

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[9] After the court expressed its view that as long as the witness was qualified as an expert, the only question was credibility of the witness to be decided by the jury, defense counsel pointed to multiple decisions of federal appellate courts holding that the court was required "to look behind his statements . . . and look to the rationale, the reason, the scientific basis for his opinions [and] when you do that . . . you find that there is no basis." Reporter's Transcript of the Hearing, April 27, 1992, at 5-7. The district court then asked:

> "The Court: ... Are you saying that its the duty of the trial judge when I hear expert testimony on complex subjects, that I have to ... say, 'well, gee, this guy is saying this astrophysics theory is such, let's look behind it.' Am I supposed to do that? ... I'm going to really see if this guy knows his stuff?' Is that my job? Yes or no?"
>
> "Mr. Woodside [defense counsel]: ... I believe the answer is yes. ..." RT at 7.

Citing the Sixth Circuit in Turpin, defense counsel said that court held that although judges should respect scientific opinion . . . nevertheless courts have a duty to inspect the reasoning of qualified scientific experts to determine whether a case should go to the jury."

The court again questioned its duty to inspect the reasoning of a qualified scientific expert, and defense counsel reaffirmed that the court had that duty:

> "Mr. Woodside: The law has evolved to the point where the bases of someone's opinion is something which must be looked into; and, therefore, appropriate inquiries [must be] made before trial, or after trial. [The court] has to [make] a determination." Id. at 8-9.

. ." Id. at 10-11.

The district court denied defendant's post-trial motion stating that it had "already ruled on those issues at trial, [and] I still believe that there is ample evidence in this trial from Drs. Lappé, Kossovsky, and Frank Vasey that was admissible and proper evidence to support the jury's verdict." RT 33-34.

Thus, defense counsel meticulously protected the record with respect to the erroneous admission of the testimony of plaintiff's expert witnesses, and defendant's briefs on appeal make the same points. The inquiries that defense counsel told the district court that it was required to make in determining the admissibility of the expert testimony and the sufficiency of the evidence were the very points that Daubert required:

> "[A] key question to be answered in determining whether a theory or technique is scientific knowledge that will assist the trier of fact will be whether it can be (and has been) tested. 'Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified; indeed, this methodology is what distinguishes science from other fields of human inquiry."' "[Has] the theory or technique been subject to peer review and publication[?]" Slip Op'n at 13-14.[7/]

The district court's committed prejudicial error in admitting plaintiff's expert testimony without any Rule 104(a) hearing and without evidence of scientific reliability.

TXO Production Corp. This Court need not reach the punitive damage questions addressed in TXO Production Corp. and Pacific Mutual Life Ins. Co. v. Haslip, 499 U.S. ___ (1991) unless it has earlier decided that (1) the plaintiffs' personal injury claim was not barred by limitations, (2) no prejudicial error occurred in its

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[7/] The Supreme Court also explained that a "'reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community."' The Court added that an "unknown technique that has been able to attract only minimal support within the community . . . may properly be viewed with skepticism." Slip Op'n at 14.

refusing to follow Brown v. Superior Court, 44 Cal.3d 1049 (1988), and (3) no prejudicial error occurred in admitting plaintiffs' expert causation testimony because any one of these errors would require reversal.

After the plurality opinion in TXO Production Corp. about all that appears to be left of Haslip's due process analysis is that punitive damages must not be "so 'grossly excessive' as to violate the substantive component of the Due Process Clause." Slip Op'n at 13.

If, as defendant contends, plaintiff had no unbarred cause of action except for invasion of her economic interests, i.e., her out-of-pocket losses, the amount of punitive damages awarded are so grossly excessive as to violate the substantive component of the Due Process Clause.

Respectfully submitted,

HUFSTEDLER, KAUS & ETTINGER

DINSMORE & SHOHL

By (signature)
Shirley M. Hufstedler

SH:cjr

cc: Laurence H. Tribe, Esq.
Dan Bolton, Esq.

APPENDIX C

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July 15, 1993

Ms. Cathy A. Catterson
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121 Spear Street, 6th Floor
San Francisco, CA 95105

RE: Hopkins v. Dow Corning Corp., No. 92-16132
(Before Judges Hug, Schroeder and Lay)

Dear Ms. Catterson:

On behalf of appellee Mariann Hopkins, I file this response in opposition to appellant Dow Corning's ("Dow") letter of July 6, 1993, in which Dow requested the panel's permission to file an extensive letter brief addressing the purported impact on this case of the Supreme Court's recent Daubert and TXO opinions. I respectfully request that this response be circulated to the members of the panel.

Dow's submission flouts the most basic rules of appellate advocacy: Dow raises arguments that have been waived; and it reargues points that have been fully briefed. As Part 1 of this letter explains, Dow advances arguments about admissibility and sufficiency that were available to it throughout this litigation but which Dow waived by failing to assert them at the proper time. As Part 2 explains, Dow has manufactured a "Rule 104(a) hearing requirement" that is utterly unsupported; Dow also selectively quotes from the post-trial hearing transcript in an effort to show that the District Court violated this non-existent requirement.[1]

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[1] As to the TXO decision, Dow's letter brief at [**A8-A9**] abandons all of Dow's previous objections to the punitive damages award except that of "gross excessiveness," and Hopkins certainly accepts Dow's concessions. However, the prior paragraph and the following paragraph are improper, as they merely reargue points earlier raised by Dow and answered by Hopkins.

1. Dow's Advancement of Waived Arguments Concerning the Admissibility and Sufficiency of Hopkins' Evidence

Dow's lengthy letter brief is targeted primarily to answering two observations made at the close of Hopkins' letter to the Court dated June 29, 1993:

> * Daubert does not help Dow because Dow chose at trial to attack only the conclusions of Hopkins' experts, rather than their methodologies.
>
> * Dow clearly waived whatever objections it may have had to the sufficiency of Hopkins' evidence.

A. Dow's Admissibility Objections

Dow's attack on the methodologies of Hopkins' experts is outrageous because it is totally new and totally unsupported by the record. Dow had an obligation to identify in its opening brief the legal arguments and record citations demonstrating an abuse of discretion by the District Court. Instead, with respect to the methodology issue, Dow waited until its reply brief to set forth a mere four citations to the record, none of which actually targeted methodology or presented any scientific proof relevant to the issue. See note 2, infra. Now, Dow seeks to add five times that number of citations in a post-argument letter brief, even though these new citations were obviously available to Dow when it filed its reply brief. In her briefing, Hopkins demonstrated that on this record there is no colorable challenge to any aspect of her experts' methodologies. The Daubert case — which addressed situations in which a party has objected to a scientific methodology, and which held that, even in such cases, general acceptance of the methodology is not necessary — is irrelevant here. Dow failed to put methodology at issue or even to introduce evidence bearing on methodology, and its last-gasp request that it be granted an exemption from accepted rules of appellate practice should be rejected.

Hopkins' observation that Dow "attack[ed] the conclusions of Hopkins' experts rather than challenging any particular principle or methodology relied on by those experts" in the District Court (Hopkins' June 29 letter; emphasis in original) was not a new argument and thus did not justify Dow's lengthy and argumentative response.

Indeed, Hopkins' mention of the methodology-conclusion distinction was merely a one sentence summary of a point argued in detail in Hopkins' brief, and highlighted directly by the Daubert decision.

Hopkins' brief specifically pointed out that Dow had filed a "narrow in limine motion," asking for limited relief (not wholesale exclusion of any expert's testimony) based on Dow's concerns about the qualifications of Hopkins' experts under Rule 702, and the reliance of Hopkins' experts on certain facts and data under Rule 703. Hopkins Br. at 46 & n.41. After demonstrating that the District Court had not abused its discretion or otherwise committed legal error in rejecting these narrow arguments (see Hopkins Br. at 48-52), Hopkins specifically argued that Dow had utterly failed to object below to the methodologies used by Hopkins' experts, and that there was no evidence in the record casting any doubt on the validity or reliability of those methodologies. Hopkins Br. at 52-55. This was hardly a passing observation; Hopkins addressed the point in detail:

> The methodology used by Hopkins' experts was the standard scientific technique, based on the use of all available data traditionally and regularly used by medical experts in determining causation. Even if the conclusion reached by Hopkins' experts that silicone leaking from Dow's breast implants caused or severely worsened her autoimmune condition could be characterized, in some sense, as "novel," the methodology used to arrive at that conclusion is generally accepted practice.
>
> * * *
>
> The methodology employed by Hopkins' experts in determining causation was carefully described by Dr. Kossovsky as "a standard established back in 1976." 7 RT 822. . . . Hopkins' other experts relied on similar methodology and reached the same conclusion. See p. 50, supra. Dow has offered no evidence or even argument that the methodology used by Hopkins' experts — including consultation of medical records, animal studies, case reports of silicone breast implants causing human autoimmune disease, and preliminary epidemiological data indicating a silicone-autoimmune linkage — is anything other than standard, accepted scientific practice.

Hopkins' Br. at 52-54 (emphasis in original; footnote omitted). See also id. at 50-51 n.46 (summarizing methodology used by each expert).

Dow specifically responded to this argument in its reply brief, in which it claimed that it had "objected both pretrial and during trial to the testimony of plaintiff's three expert witnesses on the causation issue because their opinions did not rest on any scientifically accepted basis." Reply Br. at 18 & n.31. Having thus responded to Hopkins' argument on this issue, Dow is not now entitled to bolster its position. In its reply brief, Dow chose to offer only four record citations, none of which actually demonstrated an objection to the methodology of the experts.[2] Moreover, Dow never offered any citations to evidence in the record (for example, testimony by its own experts) suggesting, let alone proving, any inadequacy in the methods used by Hopkins' experts. The testimony of Hopkins' experts that they used standard and entirely valid methodologies in rendering their opinions thus stood uncontradicted.

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[2] Dow's reply brief, at 18 n.31, listed without explanation the following record citations: 1 RT 107, 109; 2 RT 249-50; 7 RT 722, 821. But:

(1) **1 RT 107 and 109** did not even involve the testimony of any of Hopkins' three experts on causation; it involved testimony by a Dow sales representative concerning what Dow had told its sales force about possible dangers posed by its breast implants.

(2) **2 RT 249-50** involved a narrow Dow objection to Dr. Lappe's testimony, contending only that one comment about one aspect of several studies was "speculative."

(3) **7 RT 722** involved a preposterous Dow objection that Dr. Vassey's opinion regarding the cause of Mrs. Hopkins' disease was inadmissible on the ground of "inadequate foundation" because it was supposedly based "solely upon clinical observations that he has made in his practice." Dow offered no proof that clinical observation is an invalid scientific method, and it is hard to imagine that such proof could be offered. Moreover, the assertion that Dr. Vassey had relied "solely" on his clinical observations was completely repudiated by Dr. Vassey's own extensive testimony. Dr. Vassey's conclusions were expressly based on a "combination" of many factors. See 7 RT 710-712. See also 7 RT 702-09, 720, 722-26; Hopkins Br. at 23, 50 n.46.

(4) **7 RT 821** merely repeated an objection to Dr. Kossovsky's qualifications, earlier raised in Dow's in limine motion and overruled, and then abandoned by Dow on appeal.

Despite the full briefing and argument that has occurred with respect to the methodologies used by Hopkins' expert witnesses, Dow brazenly requests in footnote 5 of its letter brief (page **[A6]**) that this Court examine twenty-two new record citations on this point, which Dow now suggests (inaccurately, it turns out) will prove that the District Court ignored repeated direct attacks on the methodology used by Hopkins' three experts. That request should be rejected.[3]

---

[3] Although Dow's letter brief is improper and should not be accepted for filing, it is worth noting that a review of Dow's twenty-two record citations reveals no objection to the methodologies used by Hopkins' experts, much less any evidence that there was anything unusual or invalid about those methodologies. Instead, the citations reveal minor objections by Dow, each of which was considered and ruled on by the District Court, mostly in Hopkins' favor (often after Hopkins' counsel had narrowed or otherwise altered the nature of the questioning). Dow's objections in footnote 5 of its letter brief fall into the following categories (note that Dow's reference to Volume 1 of the record is erroneous; the page citations noted appear in Volume 2):

(1) Testimony not relevant to any issue: **2 RT 239, 240; 3 RT 24, 77, 95; 7 RT 825**.

(2) Lack of qualifications on issue: **2 RT 227, 230; 3 RT 107**.

(3) No foundation laid for testimony: **7 RT 704, 722, 821**.

(4) Question asked and answered: **3 RT 52**.

(5) Question calls for speculation: **3 RT 24; 7 RT 728**.

(6) Unduly narrative answer: **7 RT 713, 830**.

(7) Testimony refers to hearsay: **2 RT 272; 7 RT 709**.

(8) Testimony is speculative: **2 RT 250; 7 RT 704**.

(9) No objection at all, or no ground stated for objection: **3 RT 57, 75; 7 RT 741**.

In light of the content of these twenty-two objections, Dow's belated assertion that it actually attacked the methodologies — rather than just the conclusions — of Hopkins' experts is mystifying. Dow confidently states that "[d]efendant's pretrial and post-trial motions and its objections at trial leave not the slightest doubt that defense counsel attacked the admissibility of plaintiff's expert witnesses precisely on the grounds that Daubert accepted" (Letter Brief at **[A5]**), but this conclusory statement provides no record citations, and no citations directed at methodology appear elsewhere in Dow's letter brief. Confidence is no substitute for accuracy.

B. Dow's Sufficiency Objection

Turning from admissibility to sufficiency, the Court will note that Hopkins' brief demonstrated that Dow waived any sufficiency argument on causation because Dow did not move for a directed verdict on this ground, even though it moved for a directed verdict on other grounds; moreover, Dow also failed to move for judgment as a matter of law on this ground. Hopkins Br. at 55-56 & n.54. As counsel for Hopkins specifically pointed out at oral argument without rebuttal by Dow, Dow's position in its reply brief, through its total silence on the point, was: "never mind."

Dow now ignores its past abandonment of any objection to sufficiency, and has the temerity to assert: "Defendant challenged the sufficiency of the evidence to go to the jury in its directed verdict motion because plaintiff's expert witness testimony on causation was inadmissible, and no other evidence in the record existed to establish causation." Letter Brief at **[A4]**. To substantiate this flimsy argument, Dow quotes a heading from its opening appellate brief which touches on sufficiency (id.), without acknowledging that Dow conceded the waiver point by failing to answer Hopkins' waiver arguments in its reply brief or in oral argument. Although this Court should not encourage Dow's behavior by permitting the filing of its letter brief, it is important to note that Dow's new argument is demonstrably false. Dow's motion and supporting brief for a partial directed verdict, filed Nov. 15, 1991 (ER 265), which was never enlarged upon orally (see 9 RT 1109; 16 RT 2229; 17 RT 2270, 2286), did not posit that "plaintiff's expert witness testimony on causation was inadmissible, and no other evidence in the record existed to establish causation." Letter Brief at **[A4]**. Dow's directed verdict brief said nothing about the causation issue, and nothing about the admissibility of any evidence.[4]

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[4] Moreover, Dow's novel idea that a motion for directed verdict or for judgment as a matter of law could be decided after truncating a trial record by "deleting" improperly admitted evidence is insupportable; the only post-trial remedy for evidentiary errors is a new trial. As the Supreme Court explained in Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 249 (1940), arguments "that the court erred in rulings on evidence and in refusing requested instructions" are proper on a Rule 59(a) motion for a new trial, but evidence

2. Dow's Attempt to Rewrite Rule 104(a) and Malign the District Court

Although Dow never objected below, or in its briefs, or at oral argument in this Court, to the procedure by which the District Court resolved Dow's evidence objections, it now argues, for the first time in a post-argument letter brief, that the District Court refused to conduct a "Rule 104(a) hearing" — whatever that is. Dow says that in Daubert the Supreme Court "was explicit that the district court must hold a Rule 104(a) hearing to determine the admissibility of [expert scientific] testimony," and Dow claims that "[t]he district court declined to hold a Rule 104(a) hearing." Letter Brief at **[A4, A6]** (emphasis added).

If Dow means to suggest that the Supreme Court has mandated a formal, separate proceeding on each objection to the admission of expert testimony, Dow is simply wrong. Nowhere did Daubert even intimate that Rule 104(a) requires any form of "hearing." Rather, the Supreme Court simply pointed out that under Rule 104(a), which requires that preliminary questions going to the admissibility of evidence "shall be determined by the court," the district court "must determine at the outset, pursuant to Rule

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for judgment" under Rule 50(b). "Each motion," it noted, "has its own office." Id. at 249. Given the Supreme Court's analysis, and given the unfairness of granting judgment as a matter of law against a party that relied on evidentiary rulings that are later determined to be erroneous, all four circuits that have reviewed district court decisions following the tactic suggested by Dow have reversed. See Jackson v. Pleasant Grove Health Care Center, 980 F.2d 692, 696 (11th Cir. 1993); Douglass v. Eaton Corporation, 956 F.2d 1339, 1343 (6th Cir. 1992); Dixon v. International Harvester Co., 754 F.2d 573, 579-80 (5th Cir. 1985); Sumitomo Bank of California v. Product Promotions, Inc., 717 F.2d 215, 218 (5th Cir. 1983); Midcontinent Broadcasting Co. v. North Central Airlines, Inc., 471 F.2d 357, 358 (8th Cir. 1973). There is nothing in this Circuit's law to support Dow's position; for example, the strong reliance concerns articulated in the above decisions are found in this Circuit's repeated holdings that JNOV points are waived if not preserved in a directed verdict motion at the close of all evidence. See, e.g., Murphy v. City of Long Beach, 914 F.2d 183, 186 (9th Cir. 1990); Lifshitz v. Walter Drake & Sons, Inc., 806 F.2d 1426, 1428-29 (9th Cir. 1986); Farley Transportation Co. v. Santa Fe Trail Transportation Co., 786 F.2d 1342, 1346 (9th Cir. 1985).

104(a)," whether the requirements of Rule 702 are met. Daubert slip op. at 12 (emphasis added). Neither Rule 104(a), Rule 702, nor Daubert requires that the district court hold any sort of "hearing," only that the district court "determine" the issue. The law of this Circuit is clear that a district court discharges its responsibility to make such determina-tions by considering the specific objections made and then admitting or rejecting the evidence. See, e.g., United States v. Kinslow, 860 F.2d 963, 968 (9th Cir. 1988), cert. denied, 493 U.S. 829 (1989); United States v. Gere, 662 F.2d 1291, 1294 & n.1 (9th Cir. 1981); United States v. Sangrey, 586 F.2d 1312, 1315 (9th Cir. 1978).

Given the complete lack of support for Dow's newly advanced "hearing requirement" theory, and this Court's settled precedent that no such hearing is required, Dow's attempts to malign the District Court's handling of Dow's evidentiary objections are nothing short of astonishing. Using selected and heavily ellipsed quotations, Dow tries in its letter brief — for the first time in this case — to paint a picture of a District Court stubbornly unwilling to look behind the experts' qualifications and shamefully failing to discharge its obligation to rule on specific admissibility objections. Although this argument should be summarily rejected as improperly made at this late stage of the proceedings, the argument is also completely unsupported by the record.

In reality, the "incredulity" expressed by the District Court in its colloquy with Dow's trial counsel was a response to Dow's effort to revive an already waived sufficiency argument. Dow maintained that the District Court should reject the conclusions of Hopkins' experts as not credible. Contrary to Dow's selective quotation of the post-trial hearing (see Letter Brief at **[A6-A8]**), the hearing did not even address the admissibility of Hopkins' expert testimony (see attached transcript covering this portion of hearing). This is not surprising: as noted earlier, Dow had not filed a post-trial motion concerning the admissibility of Hopkins' expert testimony. Dow ignored the issue in its directed verdict motion and its motion for judgment as a matter of law, and Dow addressed the causation issue in its new trial motion only to the extent of arguing that the verdict was against the weight of the evidence.

The only reason that the dialogue concerning expert testimony between the District Court and Dow's counsel occurred at all during the post-trial hearing was that, heedless of its previous waiver of the issue, Dow audaciously inserted a sufficiency objection to Hopkins' expert testimony on causation in its reply brief supporting its motion for judgment as a matter of law. Relying heavily on a Sixth Circuit sufficiency-of-evidence opinion that had just been announced, Dow's argument was not that the evidence was inadmissible, but that "the plaintiff's evidence on the causation issue is insufficient." Reporter's Transcript at 3; see also id. at 7-8.[5] Most importantly, nothing in Dow's post-trial reply brief or in its arguments at the hearing on its post-trial motions touched in any way on Rule 104(a). Dow's reference to Daubert's discussion of Rule 104(a) is thus irrelevant.

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[5] Dow relied on Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349 (6th Cir.), cert. denied, 113 S. Ct. 84 (1992). Turpin borrowed from administrative law doctrine to allow the district court to "judge for itself" the sufficiency of expert testimony after taking a "hard look" at the "validity of the reasoning process by which various competing qualified experts have reached their conclusions." 959 F.2d at 1350, 1352-53. Dow argued that "[h]ere, plaintiff's expert evidence suffers the same fatal flaws inherent in the expert testimony rejected as insufficient by the Turpin court," because one of Hopkins' experts had "[t]he earmarks of an evasive witness" who would "bob and weave," raising "a cloud of suspicion." Dow's Reply Memorandum in Support of Motions for Judgment as a Matter of Law or, in the Alternative, for a New Trial, filed March 16, 1992, at 4, 7-8. Despite the Turpin court's failure to consider the Seventh Amendment and Erie implications of substituting a judge's view on the credibility of an expert's conclusions for the jury's views, in a case arising under state law, Dow strenuously — and improperly, given its waiver — urged the District Court to adopt the Turpin approach to sufficiency-of-evidence analysis.

Addressing Dow's Turpin argument, the District Court modestly expressed misgivings about its ability, simply by virtue of being "appointed for life," to "really see if [a scientifically qualified expert] knows his stuff." Reporter's Transcript at 7. Even so, the District Court noted that "if someone comes here and says something that defies the law of science . . . I don't have to take that at face value." Id. at 6. To read into the District Court's rejection of Dow's Turpin theory on sufficiency a refusal by the District Court fully to examine all evidentiary objections is ludicrous.

For all the above reasons, Dow's request to have its letter brief filed should be rejected.

Sincerely,

(signature)
Laurence H. Tribe

cc: Shirley M. Hufstedler, Esq.
Frank C. Woodside, III, Esq.

Supreme Court, U.S.
FILED
NOV 30 1994
OFFICE OF THE CLERK

No. 94-861

In The

Supreme Court of the United States

October Term, 1994

DOW CORNING CORPORATION,

Petitioner,

v.

MARIANN HOPKINS,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

REPLY TO OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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11 pp

TABLE OF CONTENTS

Page

RESPONDENTS ARGUMENTS IN OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI ARE SUPPORTED NEITHER BY THE RECORD NOR APPLICABLE LAW 1

I. AT EVERY STAGE OF THE PROCEEDINGS BELOW, PETITIONER OBJECTED TO THE ADMISSIBILITY OF RESPONDENT'S OPINION TESTIMONY BECAUSE THE MEANS OF REACHING THEIR OPINIONS HAD NO ACCEPTABLE SCIENTIFIC BASIS 1

II. PETITIONER PROPERLY PRESERVED ITS DUE PROCESS QUESTION 4

TABLE OF AUTHORITIES

Page(s)

Browning-Ferris Indus. v. Kelco Disposal, Inc., 492 U.S. 257 (1989) 5

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. ___, 113 S. Ct. 2786 (1993) 1, 2, 3, 4

Honda Motor Co., Ltd. v. Oberg, ___ U.S. ___, 114 S. Ct. 2331 (1994) 6

Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1 (1991) ...4, 5

United States Constitution

Fifth Amendment..... 5

Fourteenth Amendment..... 5

Federal Rules of Civil Procedure, Rule 59..... 5

RESPONDENT'S ARGUMENTS IN OPPOSITION TO THE PETITION FOR WRIT OF CERTIORARI ARE SUPPORTED NEITHER BY THE RECORD NOR APPLICABLE LAW

Respondent does not deny the importance of the questions presented nor the ripeness of those questions for decision by this Court. Instead, Respondent argues that the questions were not preserved in the lower courts. Respondent is mistaken.

I. AT EVERY STAGE OF THE PROCEEDINGS BELOW, PETITIONER OBJECTED TO THE ADMISSIBILITY OF RESPONDENT'S OPINION TESTIMONY BECAUSE THE MEANS OF REACHING THEIR OPINIONS HAD NO ACCEPTABLE SCIENTIFIC BASIS

Petitioner's objection to the admission of Respondent's expert testimony commenced with its Motion *in limine* to Exclude Expert Testimony in which it argued that "under Federal Rule of Evidence 703, the Court shall exclude any testimony by plaintiff's experts where there is no acceptable or reliable basis for their opinion." (June 18, 1991 Motion at 2-3.) The argument was repeated in objections to the admission of the experts' testimony during trial. Its objections were even more extensively argued in Petitioner's post-trial motions.[1]

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[1] Petitioner's supplemental letter brief, filed after *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. ___, 113 S. Ct. 2786 (1993) came down and before the Court of Appeals filed its opinion, included substantial quotations from the Petitioner's arguments supporting its post-trial motions. That letter brief is set forth in the Appendix to Respondent's Opposition to

On appeal, the argument was renewed in detail charging prejudicial error in the admission of the testimony of Respondent's expert witnesses because their opinions were not based on any methodology that had been generally accepted by any relevant scientific community; there was no scientific basis for the opinions; and the opinions were not sufficiently reliable to be admitted. (Petitioner/Appellant's Opening Brief, pp. 44-50.) The attack was elaborated in its Petition for Rehearing arguing that this Court's opinion in *Daubert* fully supported its prior objections to admissibility. (Petition for Rehearing, pp. 6-10.)

Respondent argues that the question was nevertheless not preserved because Petitioner is only claiming error in the denial of its motion for summary judgment which was based, in part, on the ground that Respondent had failed to produce any admissible evidence on causation because her expert testimony on the subject was not based on any scientifically acceptable method. (OPC, p. 16.) In its Petition before this Court and its briefs below, the prejudicial error claimed is and was the inadmissibility of Respondent's causation testimony at trial because it failed to meet any of the criteria for scientific reliability.[2]

Petition for Writ of Certiorari ("OPC") as Appendix B, pp. A-3 through A-9.) Those arguments make unmistakably clear that the challenge to admissibility was on the grounds later accepted in *Daubert*.

[2] Petitioner did not attack denial of its summary judgment motion in the Court of Appeals because the law of the Circuit foreclosed that attack when the appeal is from a judgment entered after a full trial on the merits. The Petition does make a

Respondent argues that Petitioner was required to raise the question of the sufficiency of Respondent's expert causation testimony at the directed verdict stage. (OPC, p. 18.) Petitioner did so. 18 RT 2286-87. The Petitioner thereafter raised the precise question in its opening brief on appeal, contending that the methodology by which the expert witnesses reached their opinions was not scientifically acceptable. (Petitioner's/Appellant's Opening Brief, pp. 45-50.) Respondent incorrectly contends that (1) Petitioner attacked only the conclusions of plaintiff's treating physicians (it did not) and that (2) it argued only that the experts' conclusions were not expressed at the level of reasonable medical probability. (OPC, p. 18.) The record establishes the contrary.

Finally, Respondent appears to contend that the question was not preserved below because Petitioner did not make "a *Daubert*-style analysis of *the methodology* of Hopkins' experts." [Emphasis in original.] (OPC, p. 20.) The substance of the numerous attacks in the lower courts on the admissibility of the expert testimony was not materially different from the *Daubert* analysis.[3] Petitioner

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policy argument that the admissibility question should be decided on summary judgment; accordingly, to encourage that result, it is desirable to be able to seek review of the error in denying summary judgment. However, summary judgment error was not the basis of the appeal in the lower court, and it is not the foundation of the Petition before this Court.

[3] Although Petitioner did not use the word "methodology" in its objections to the experts' testimony in the trial court, it invoked the identical concept using the words "scientific basis," "steps," and "scientific foundation." On appeal, Petitioner used the explicit term "methodology" in attacking the lack of any scientific basis for the expression of Respondent's experts' opinions.

obviously could not have relied on this Court's *Daubert* opinion before it came down. After it did, Petitioner attacked the admissibility of the testimony precisely on *Daubert* grounds.

II. PETITIONER PROPERLY PRESERVED ITS DUE PROCESS QUESTION

Respondent argues that Petitioner did not raise its due process arguments below because it did not renew its due process arguments in its Petition for Rehearing or in its motion to stay mandate in the Court of Appeals. (OPC, p. 21.) The statement is not accurate.

As Respondent acknowledges, Petitioner challenged the validity of the punitive damage award because California's punitive damage law does not meet the constitutional criteria prescribed by *Pacific Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 21-22 (1991). In its initial motion to stay the mandate after rehearing had been denied, Petitioner did not present the due process point because the mandate would have gone down to the district court within a few days and preparation of a certiorari petition had only begun. Petitioner presented the precise due process point to the Court of Appeals in its renewed motion to stay or recall the mandate pending its filing of its certiorari petition with this Court; the motion was supported by the declaration of Shirley M. Hufstedler to which was annexed the draft of the certiorari petition that had then been sent to the printer.[4] A copy of the Court of Appeals'

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[4] The draft sent to the Court of Appeal, with non-substantive corrections, is the Petition filed with this Court.

order granting the motion to stay the mandate is annexed hereto as Appendix A.

Respondent contends that Petitioner has taken inconsistent positions with respect to its due process attack. (OPC, p. 22.) Petitioner is again mistaken.

Analysis of the due process issue challenging an award of punitive damages in a diversity action is a two-step process: (1) The state law of punitive damages must initially be examined to determine whether it meets minimum due process standards required by the Fourteenth Amendment, as interpreted and applied in *Haslip,* 499 U.S. at 21-22; and (2) federal law must be examined to determine whether the federal standards of review of such awards meet the due process minima required by the Fifth Amendment. Petitioner has consistently argued in this Court and below that California punitive damages law does not meet the constitutional minima of *Haslip;* California law does not provide constraints on jury discretion that have been provided by Alabama and Oregon. (Petition, pp. 17-18.) The Court of Appeals did not apply California law in reviewing compliance with *Haslip;* instead, it applied the criteria adopted in Alabama, which California has never adopted. The Court of Appeals did not reach the second stage of the due process inquiry. (Petition, pp. 16-18.)

Respondent's contention that this Court in *Browning-Ferris Indus. v. Kelco Disposal, Inc.,* 492 U.S. 257 (1989) held that federal review pursuant to Rule 59 of the Federal Rules of Civil Procedure meets constitutional standards is incorrect. (OPC, p. 21.) The due process issue was neither raised nor decided in *Browning-Ferris.* The Court decided

only that "neither federal common law nor the Excessive Fines Clause of the Eighth Amendment provides a basis for disturbing the jury's punitive damage award in this case." 492 U.S. at 280.

Respondent also argues that the common law provides ample guidance on the amount of procedural process that is due in a federal court reviewing a punitive damage award in a diversity case, citing *Honda Motor Co., Ltd. v. Oberg*, ___ U.S. ___, 114 S. Ct. 2331 (1994). Although that case is relevant in other particulars, it provides no guidance on the question presented because that case was not tried in a federal court.

Respondent complains that the Petition does not explain how it was hurt by the lack of any meaningful judicial scrutiny of the punitive award against it. (OPC, p. 23.) The Petition argued that three levels of standardless discretion resulted in an award of punitive damages that arbitrarily deprived Petitioner of its property. (Petition, pp. 17, 23.) The absence of any meaningful criteria to guide the jury and any meaningful judicial review permitted the jury to vent its spleen against a big corporation, without any significant local presence, and at the same time to express its sympathy for Respondent. The result is to force Petitioner to pay Respondent and her lawyers many millions of dollars as a quasi-criminal fine with none of the procedural protections that would be required to uphold a $500 fine imposed in a criminal case.

The questions presented by this Petition have been properly raised below, and they are ripe for decision by this Court.

Dated: December 1, 1994

Respectfully submitted,

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APPENDIX A

NOT FOR PUBLICATION

UNITED STATES COURT OF APPEALS

FOR THE NINTH CIRCUIT

MARIANN HOPKINS, Plaintiff-Appellee, v. DOW CORNING CORPORATION, Defendant-Appellant.	NO. 92-16132 D.C. No. CV-88-04703-TEH ORDER ("Filed" stamped November 14, 1994)

Before: HUG, Circuit Judge.

Dow Corning's November 9, 1994 motion to stay the issuance of the mandate is hereby GRANTED. Dow Corning has furnished the court with a copy of the petition for the writ of certiorari that was sent to the printer and will be filed with the United States Supreme Court when printed.

GOOD CAUSE APPEARING, the stay is granted to and including November 18, 1994. Provided that the petition for a writ of certiorari is filed with the Supreme Court on or before that date, this stay will continue pending final disposition of the petition by the United States Supreme Court.